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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

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UNITED STATES OF AMERICA

v.

CHRISTOPHER CLOUGH

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17-CR-37-01-JL
December 12, 2018
9:10 a.m.

TRANSCRIPT OF JURY TRIAL
DAY TWO - MORNING SESSION
BEFORE THE HONORABLE JOSEPH N. LAPLANTE

APPEARANCES:

For the Government:

Seth R. Aframe, AUSA
Charles Rombeau, AUSA
U.S. Attorney's Office

For the Defendant:

Patrick J. Richard, Esq.
Richard Law Office

Robin Gagne, Esq.
Gagne Law Office

Court Reporter:

Susan M. Bateman, LCR, RPR, CRR
Official Court Reporter
United States District Court
55 Pleasant Street
Concord, NH 03301
(603) 225-1453

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1 P R O C E E D I N G S

2 (IN COURT - NO COURT OR JURY PRESENT)

3 THE CLERK: In the matter of United States of
4 America versus Christopher Clough, criminal case number
5 17-CR-37-01-JL, the government has premarked Exhibits 100
6 through 902. All exhibits are admitted.

7 Thank you.

8 (IN ANTEROOM WITH THE COURT AND COUNSEL)

9 THE COURT: Okay. We're here in the Clough
10 criminal case, and I just want to put on the record the
11 discussion I just had with counsel. I'm in chambers here
12 with counsel for both sides.

13 The U.S. Marshal Service reported to me this
14 morning that a court security officer had observed a
15 conversation between one of the jurors, who appears to be
16 Juror No. 1, Mr. Yanis, and an adult woman who after talking
17 with counsel here today it turns out is likely to be the, I
18 guess partner of the defendant's father.

19 MR. RICHARD: Correct.

20 THE COURT: Do you know her name?

21 MR. RICHARD: I believe the first name to be Gayle.

22 THE COURT: We'll just call her Gayle for now. The
23 court security officer reported that when the juror came in
24 and came through security today the juror sat down on a bench
25 nearby to apparently change his shoes or something, and after

1 Gayle came through security -- and Gayle had some questions
2 about why she was being asked to do things like remove her
3 belt and the things people ask court security officers a lot,
4 by the way -- she approached the juror and they had a
5 conversation which lasted a couple of minutes. The court
6 security officer said it was not just a passing exchange of
7 pleasantries; it was a conversation. But the court security
8 officer did not hear any of the substance of the
9 conversation.

10 After that Gayle sort of circled back to security
11 and engaged security, the court security officers in a
12 conversation regarding whether she could have coffee in the
13 courthouse, and during that Gayle made reference to the fact
14 that the individual over there she had just been talking to
15 was a juror and he was allowed to have coffee so she
16 questioned why she wasn't allowed to have coffee.

17 So I've sat down and I've explained this to
18 counsel, and as I was considering how to -- everyone agrees
19 that the Court needs to examine the juror to determine if the
20 juror has been in any way compromised by this contact with
21 someone close to the defendant.

22 Defense counsel, by the way, has already assured
23 the Court that he will have a conversation with Gayle, if
24 that is her name, by the way, and just warn her about having
25 contact with jurors or any other kind of interference with

1 the proceeding. We all agree, though, that the Court needs
2 to examine the juror and one of the prosecutors suggested
3 that it might be a good idea if the Court did that without
4 all the counsel present, which I was a little bit concerned
5 about intimidating the juror or spooking the juror too much
6 with a conversation with a small conference room here full of
7 four lawyers, two law clerks, a court reporter and Charli
8 Pappas, the deputy clerk.

9 So all counsel agreed that the Court could examine
10 the juror and then report back to counsel and they could
11 request any appropriate relief if they desired it. I think
12 that's a better idea because I think it's less likely -- when
13 I say a better idea, what I mean is it's a better idea to
14 examine the juror outside the presence of counsel in the
15 first instance at least to avoid alarming the juror or in any
16 way unnerving the juror. Do all counsel agree?

17 MR. AFRAME: Yes.

18 MR. ROMBEAU: Yes.

19 MR. RICHARD: Yes on behalf of Mr. Clough.

20 THE COURT: All right. I appreciate that and I
21 will do this as expeditiously as I can and then get back to
22 you.

23 MR. RICHARD: Should I take the time now to speak
24 with Gayle?

25 THE COURT: Yes.

1 (Counsel leave anteroom and Juror No. 1 brought in)

2 THE COURT: Hi, Mr. Yanis. Good morning. Have a
3 seat, if you would, anywhere that makes you comfortable. I
4 don't want to alarm you in any way.

5 THE JUROR: Okay. All right.

6 THE COURT: Or make you feel as if you've done
7 anything wrong. I have to ask you a couple questions,
8 though.

9 THE JUROR: Sure.

10 THE COURT: It was reported to me by a court
11 security officer that after you came through security this
12 morning you had a conversation with a woman downstairs, a
13 woman engaged you as you were changing your shoes or
14 something and talked to you for a couple of minutes.

15 THE JUROR: All right. Well, she was asking about
16 what floor to go on and basically I said, well, I'll be more
17 than glad to take you up there. We certainly didn't talk
18 anything particular. I didn't know if she was a juror or not
19 or anything like that.

20 THE COURT: All right. So you thought she might
21 even be a juror?

22 THE JUROR: I didn't know. I mean -- and she asked
23 me about my coffee. She was like, oh, I didn't know we could
24 bring those in. I'm like, yeah, yeah, you can't bring in
25 electronic devices or whatever like that but you can bring

1 your coffee in.

2 THE COURT: Did she identify herself?

3 THE JUROR: She did not.

4 THE COURT: Did she give you any indication that
5 she knew you were a juror?

6 THE JUROR: She did not -- I mean other than I did
7 have my juror thing on.

8 THE COURT: You had your juror tag on and for the
9 record, he just pointed to the lanyard and the juror card he
10 has around his neck. Did she identify that and point out to
11 you that you're a juror or anything --

12 THE JUROR: No, nothing like that.

13 THE COURT: Other than talking about logistics like
14 the location of the courtroom or whether coffee was allowed,
15 was there anything else you talked about?

16 THE JUROR: Negative.

17 THE COURT: Do you know who she was?

18 THE JUROR: I have no idea.

19 THE COURT: Okay. That's fine. You didn't do
20 anything wrong, but it came to my attention, and for me to
21 explain to you why this is important would actually overdo
22 it, okay?

23 THE JUROR: Okay.

24 THE COURT: You haven't done a thing wrong.

25 Everyone in our system needs to be treating you frankly with

1 the most respect and with the most deference almost, letting
2 you go about your business and doing what you need to do,
3 because all of the influences on you have to be in that
4 courtroom: attorneys, evidence, exhibits, testimony and the
5 like.

6 THE JUROR: I understand.

7 THE COURT: It's important for us to make sure
8 you're not influenced by outside sources. That's all. So do
9 you have any concerns at all about the conversation you had
10 with whoever this woman was?

11 THE JUROR: Negative. No.

12 THE COURT: You still have no idea who she was?

13 THE JUROR: I have no idea.

14 THE COURT: All right. Do you have any questions
15 for me?

16 THE JUROR: I do not.

17 THE COURT: Okay, good. We're going to get started
18 here in about five minutes.

19 THE JUROR: I mean, so I would just tell you this.
20 I mean, she was an older woman and I just thought I was
21 offering my services to help her through to wherever she
22 needed to go. I try to be a helpful person.

23 THE COURT: For what it's worth, you handled it
24 precisely as I would have handled it in your shoes. I can't
25 think of even a suggestion I can offer you about how to

1 handle something like that because as far as you knew, and as
2 far as you know, this is just a woman entering the
3 courthouse.

4 THE JUROR: That's it.

5 THE COURT: It's a public courthouse, by the way.
6 Everybody's allowed to come in and out of here and watch
7 anything. You will probably see spectators coming in and out
8 of this trial. I think there's a group of high school
9 students that are going to watch half the trial this morning.

10 All right. I really appreciate this. Sorry if we
11 unnerved you in any way. Once in a while these little things
12 come up and we have to look into it.

13 THE JUROR: I understand.

14 THE COURT: Okay, thanks. Get back to the jury,
15 and you don't need to describe what's going on. They're
16 going to be curious. I'll explain when we're all out there
17 together, all right?

18 THE JUROR: Excellent. Thank you.

19 THE COURT: Oh, one more question. I should have
20 asked you this. Did your conversation with the woman come up
21 with the rest of the jury this morning as you sat there
22 waiting for trial to start?

23 THE JUROR: Negative.

24 THE COURT: Didn't even come up?

25 THE JUROR: Negative.

1 THE COURT: Understood. Thank you. All right.

2 (Juror No. 1 leaves anteroom and counsel return)

3 THE COURT: All right. We have reconvened in
4 chambers with counsel for both parties. I have examined -- I
5 have invited into this chambers the juror, Juror No. 1, Mr.
6 Yanis. I asked him a couple of questions about his
7 interaction with the woman downstairs. He doesn't know her
8 name. He doesn't know who she was. He thought she might
9 even be another juror.

10 She asked questions about how to get up to the
11 courtroom and whether she was allowed to have coffee. They
12 talked about those types of very benign issues, and he still
13 doesn't know who she was. I didn't tell him who she is, but
14 we explored it together and he told me everything there was
15 about the conversation which -- he was -- he basically
16 characterized it as, I thought she was an older woman in need
17 of assistance and I tried to provide it. That was his
18 approach.

19 He's sort of a -- I remember him from jury
20 selection. He is a juror with a gregarious personality, the
21 type of person you would expect to reach out to anybody who
22 looked like they needed any assistance whatsoever, and that's
23 sort of how he came across in this examination as well, but
24 it doesn't appear that he has any knowledge of who that was.
25 I think he might put it together as he sits in the courtroom

1 for two weeks here.

2 MR. RICHARD: Sure.

3 THE COURT: But didn't discuss anything of
4 substance about the trial, only about the courthouse and the
5 logistics of getting from point A to point B.

6 Is everybody satisfied with that examination?

7 MR. AFRAME: Yes.

8 MR. RICHARD: I am, yes.

9 THE COURT: Does anybody request any relief based
10 on that interaction between the woman and the juror?

11 MR. AFRAME: The government doesn't.

12 MR. RICHARD: Mr. Clough does not.

13 THE COURT: Okay, we'll proceed. When I give the
14 jury their preliminary instructions which I'm about to give,
15 I'll just make a few references to, you know, it's best not
16 to be interacting with people around the courthouse other
17 than the most basic stuff.

18 Can you report what you --

19 MR. RICHARD: I can let the Court know that I spoke
20 with Ginny. Ginny was her first name, not Gayle.

21 THE COURT: You had the G right.

22 MR. RICHARD: Yeah, I did. She indicated to
23 me there was a discussion about bringing coffee in and then
24 just about getting up to the third floor. I have informed
25 both her and Mr. Clough's father that if they see people they

1 recognize to be jurors not to have any conversation with them
2 whatsoever beyond basic pleasantries. And I think both
3 parties understand that it's the best practice and I think
4 that this won't happen again.

5 THE COURT: Understood. I appreciate that.

6 MR. RICHARD: You're welcome.

7 THE COURT: And we'll get started.

8 MR. RICHARD: Thank you.

9 THE COURT: Thank you, counsel.

10 (Conclusion of anteroom conference)

11 (IN COURT - JURY PRESENT)

12 THE CLERK: The Court has before it for
13 consideration this morning day two of the jury trial in
14 Criminal Case 17-CR-37-01-JL, United States of America versus
15 Christopher Clough.

16 Judge, would you like me to swear the jury in?

17 THE COURT: Please.

18 (Deputy clerk swears in the jury)

19 THE COURT: Good morning, everyone. Welcome back
20 to court.

21 One of you asked yesterday about whether you could
22 take notes, and as you've obviously discovered, the answer is
23 yes and you each have a notebook.

24 I'm going to give you some preliminary instructions
25 now. You don't need to take notes about any of this. You're

1 free to take notes about anything I say, but you don't need
2 to take any notes. You're free to just sit back and listen
3 if you like. This is just sort of a preliminary set of
4 instructions just to let you know what's going to happen in
5 trial and how to interpret it and how to conduct yourselves
6 as jurors.

7 At the end of the trial I'm going to give you the
8 official set of jury instructions, it's called the jury
9 charge. That's the official Court's instructions describing
10 the law and how to apply it to the facts. This is just sort
11 of a preview.

12 At that point you'll each be given a copy of the
13 instructions, a written copy that you can take with you into
14 jury deliberations and use and refer to while you actually
15 deliberate. So anything I say now is going to be repeated in
16 much greater detail at the end of the trial. So if you're
17 worried about keeping track of what I say, don't worry,
18 you're going to get it in writing later on.

19 So before we start the trial -- can everybody hear
20 me okay? I don't want to use the microphone unless I have to
21 so if you can all hear, that's fine.

22 I want to tell you what will be happening in the
23 trial. I want to describe to you how the trial will be
24 conducted and explain what we will be doing; what you'll be
25 doing, what the lawyers will be doing, and what I'll be doing

1 as the Court.

2 At the end of the trial I will give you more
3 detailed guidance in writing about how you are to go about
4 rendering your decision, but now I simply want to explain how
5 the trial will proceed.

6 This criminal case has been brought by the United
7 States government. I will sometimes refer to the government
8 as the prosecution. The United States government is
9 represented at the trial by two Assistant United States
10 Attorneys, Seth Aframe and Charles Rombeau who you met
11 yesterday.

12 The defendant, Christopher Clough, is represented
13 by his lawyers, you met them yesterday as well, Patrick
14 Richard and Robin Gagne.

15 Gagne, Gagne, how would you like me to pronounce
16 that?

17 MS. GAGNE: Gagne.

18 THE COURT: Gagne.

19 The defendant has been charged by the United States
20 Attorney with violation of federal law. He is charged with
21 receiving kickbacks and conspiring to pay and receive
22 kickbacks in violation of federal law.

23 The charges that the defendant is facing are
24 contained in the indictment. The indictment is simply the
25 description of the charges made by the United States Attorney

1 against the defendant. It is not evidence of anything. The
2 defendant pleaded not guilty to the charges against him and
3 denies committing the crimes. The defendant is presumed
4 innocent and may not be found guilty by you unless all of you
5 unanimously find that the United States Attorney has proven
6 the defendant's guilt beyond a reasonable doubt.

7 The first step in the trial will be the opening
8 statements. That's what you'll hear next. Just as the
9 indictment is not evidence, neither are the opening
10 statements evidence. Their purpose is only to help you
11 understand what the evidence will be and what the United
12 States Attorney will try to prove. In fact, the defendant
13 doesn't even need to make an opening statement. He may, he
14 may not, but he has no burden of proof and if he doesn't make
15 an opening statement, you aren't to draw any inference from
16 that whatsoever.

17 After the opening the United States Attorney will
18 offer evidence that it says will support the charge against
19 the defendant. The United States Attorney's evidence in this
20 case will consist of the testimony of the witnesses as well
21 as documents which are called exhibits. Some of you have
22 probably heard the terms circumstantial evidence and direct
23 evidence. Don't be concerned with these terms. You are to
24 consider all the evidence given in this trial, both
25 circumstantial and direct. You don't need to figure out

1 which it is. If you hear it, it's evidence and you can
2 consider it.

3 After the United States Attorney's evidence, the
4 defendant's lawyer may present evidence in the defendant's
5 behalf but is not required to do so. I remind you that the
6 defendant is presumed innocent and the United States Attorney
7 must prove his guilt beyond a reasonable doubt. The
8 defendant does not have to prove his innocence.

9 After you have heard all the evidence on both
10 sides, the prosecution and the defendant will be given time
11 for their final arguments. After the evidence is over
12 they'll argue to you about what the evidence means and what
13 conclusions you should draw from that evidence.

14 Now, the final part of the trial occurs when I
15 instruct you about the rules of law which you are to use in
16 reaching your verdict. I will give each of you a written
17 copy of my instructions and I will read them to you out loud.
18 After hearing my instructions, you will leave the courtroom
19 together to make your decision. Your deliberations will be
20 secret. You will never have to explain your verdict to
21 anyone. You have to return a verdict, but you never have to
22 explain it to anyone individually or as a group.

23 Now that I have described the trial itself, let me
24 explain the jobs that you and I are to perform during the
25 trial. I will decide what rules of law apply to this case.

1 I've already given that a lot of thought and I know what I'm
2 prepared to tell you about it, but there will be times during
3 the trial where I will have to make interim decisions about
4 the law.

5 You will decide whether the United States Attorney
6 has proved beyond a reasonable doubt that the defendant has
7 committed the crimes of receiving kickbacks and conspiring to
8 pay and receive kickbacks. You must base that decision only
9 on the evidence in the case and my instructions about the
10 law.

11 In order to sustain its burden of proof for the
12 crime of receiving kickbacks as charged in the indictment,
13 the prosecution must prove the following elements beyond a
14 reasonable doubt:

15 1. That Christopher Clough solicited or received
16 remuneration directly or indirectly, overtly or covertly, in
17 cash or in kind.

18 2. That the remuneration was paid in return for
19 purchasing, ordering, or arranging for or recommending
20 purchasing or ordering any good, service or item for which
21 payment was made in whole or in part under a federal health
22 care program.

23 3. That Christopher Clough acted knowingly and
24 willfully.

25 Now, in order to sustain its burden of proof for

1 the crime of conspiring to pay and receive kickbacks as
2 charged in the indictment, the United States Attorney must
3 prove the following elements beyond a reasonable doubt:

4 1. That the agreement specified in the indictment,
5 not some other agreement or set of agreements, existed
6 between at least two people to commit the crime of paying and
7 receiving kickbacks.

8 2. That Christopher Clough willfully joined in
9 that agreement.

10 3. That one of the conspirators in the conspiracy,
11 in the agreement, committed an overt act in an effort to
12 further the purpose of the conspiracy. Actually did
13 something, committed an overt act.

14 Now, if you find the defendant guilty it will then
15 be my job, the Court's job, to decide what punishment should
16 be imposed. In considering the evidence and arguments that
17 will be given during the trial you should not guess about
18 punishment. You should not guess about the sentence. That's
19 not the jury's job; that's the Court's job. It should not
20 enter into your considerations or discussions at any time.

21 During the course of the trial you should not talk
22 with any witness or the defendant or with any of the lawyers
23 in the case. Please don't talk with them about any subject
24 at all.

25 In addition, during the trial you should not talk

1 about the trial with anyone else; not your family, not your
2 friends, not the people you work with, not even your fellow
3 jurors, not about the trial. You should not discuss the case
4 among yourselves until I've instructed you on the law and you
5 have gone to the jury room to make your decision to
6 deliberate at the end of the trial. It's important that you
7 wait until all the evidence is received and that you have
8 heard my instructions on rules of law before you deliberate
9 among yourselves.

10 Just a note about what I already said about not
11 talking with any witnesses or the defendant or any attorneys.
12 It's best not to talk to anybody in the courthouse. That
13 doesn't mean you have to be impolite and ignore people, but
14 when you encounter people on the courthouse grounds, when you
15 come through the doors and up the stairs, it's best not to
16 talk to anybody at all. You're the most important people in
17 this proceeding. You're the judges of the facts. You're the
18 ones who are going to determine what happened here. In other
19 words, the important decisions in this case have been
20 assigned to you under our system of government, which is the
21 best government in the world. Under that system, your
22 decision must be based on what happens right here in this
23 well of the courtroom, from this witness stand, the podium
24 from which the questions are asked, that's everything.

25 Anything that happens on your way in, on your way

1 out, in the media, we'll talk about all of that, has nothing
2 to do with your job or your sworn duty as jurors in this
3 case. So it's best not to talk to anybody as you come into
4 the courthouse and leave.

5 Now, you shouldn't communicate with anyone else or
6 the outside world about this case during any part of the
7 trial. This prohibition applies to both receiving
8 information and to giving information. Do not e-mail about
9 it or text or tweet or instant message or share any
10 information about it on any blog or website, including
11 Facebook, Google, Linked-In, Snapchat, Instagram or YouTube.

12 I want to ask the high school students, did I leave
13 anything out? The bottom line is don't do it.

14 All right. You may not use any similar technology
15 or social media, even if I have not specifically mentioned it
16 here, to disseminate any information about the trial during
17 the trial whether to your family or co-worker or to the world
18 at large because that would violate my instructions and the
19 Court's rules.

20 Let me add that during the course of the trial
21 you'll receive all the evidence you properly may consider in
22 order to decide the case. Because of this, you should not
23 attempt to gather any information on your own which you think
24 might be helpful. Do not engage in any outside reading on
25 this case, the matters in the case, or the individuals

1 involved in the case, not on the Internet, not in the
2 library, and not in your own home. Do not attempt to visit
3 any places mentioned in the case and do not in any other way
4 try to learn about the case outside the courtroom.

5 Now that the trial has begun, you must not read
6 about it in the newspapers or watch or listen to television
7 or radio reports or read Internet news reports, blogs, chat
8 rooms or anything else about what is happening here.

9 The reason for these rules, as I am certain that
10 you will understand, is that your decision in this case must
11 be based solely on the evidence presented at trial. I expect
12 you will inform the Court as soon as you become aware that
13 you or any other member of the jury has violated these rules
14 and either disseminated information or received information
15 from some outside source.

16 Now, at times during the trial a lawyer will make
17 an objection to a question asked by another lawyer or to an
18 answer given by a witness. That simply means that the lawyer
19 is requesting that I, as the Court, make a decision on a
20 particular rule of law, rule of evidentiary law. Do not draw
21 any conclusions from any such objections or from any of my
22 rulings on the objections. They only relate to the legal
23 questions that I must determine and shouldn't influence your
24 thinking at all.

25 If I sustain an objection, if I say sustained, the

1 witness can't answer the question. Don't attempt to guess
2 what that answer might have been had I allowed the question
3 to be answered. Similarly, if I tell you not to consider a
4 particular statement, if I say strike that, disregard it, you
5 should put that statement out of your mind, and you may not
6 refer to that statement in your later consideration or
7 deliberations of this case.

8 During the course of the trial I may ask a question
9 of a witness, me. Once in a while I may interrupt and ask
10 the witness a question. If I do, a couple things to remember
11 about it. It doesn't mean that I have an opinion about the
12 facts in this case. I do not. Secondly, my questions are
13 not any more important than any question that a lawyer asks
14 in any trial. The fact that the Judge asks it doesn't mean,
15 oh, that's especially important. If I ask a question, it's
16 probably because I'm confused and don't understand the answer
17 or I think it could be clarified a bit to help you, but it
18 doesn't make it a particularly important question so there's
19 no need to emphasize the question or the answer over anything
20 else you hear at the trial.

21 Now let me clarify something that you may wonder
22 about later. During the course of the trial I may have to
23 interrupt the proceedings to confer with the attorneys about
24 rules of law which should apply here. Sometimes we talk here
25 at the bench over at sidebar where most of you visited during

1 jury selection, sometimes we'll do it just right here in open
2 court, but sometimes I'll even excuse you and send you into
3 the jury deliberation room to wait for a couple of minutes.
4 That's because I think the conversation is going to take, you
5 know, maybe longer than two or three minutes and I want you
6 to be comfortable and not have to sit there silently and not
7 moving and wondering what's going on. I'll just let you
8 relax in the jury deliberation room.

9 When that happens, the purpose is usually to keep
10 things moving more quickly. Even though it might feel like
11 the trial is slowing down, generally the things we work out
12 on those breaks make the trial move more quickly. The same
13 thing might happen at the beginning of a day sometimes.
14 Sometimes an issue will come up at 9 o'clock when you're all
15 ready to go and we don't get out into the courtroom. It
16 happened this morning actually. Something happens and we
17 have to have a conversation about it. It's much better to do
18 that than let it fester and then pop up during a trial and
19 derail things in a real way. So that's why sometimes you'll
20 find yourselves waiting instead of listening to the evidence.

21 Now, in this trial you have the permission of the
22 Court to take notes. The fact that you have been given
23 permission to take notes does not in any way require you to
24 do so. In other words, if you're not a note taker, you hated
25 taking notes in high school or college or whatever and you

1 don't like taking notes, you don't have to take notes just
2 because the person next to you is taking notes and might be a
3 great note taker. But if a person around you is a great note
4 taker, that doesn't mean you can check out mentally and
5 daydream to rely on their notes later. It's your obligation
6 to observe the evidence and remember the evidence, and note
7 taking is going to help you do that. Some of you do that in
8 some situations.

9 A few rules about taking notes. First, take notes
10 sparingly. Do not try to summarize all of the testimony.
11 Notes are for the purpose of refreshing your memory about
12 things like names or dates or times, relationships, figures.
13 You'll know what you want to take notes about because you
14 know how your memory works, but they're not about trying to
15 transcribe the testimony.

16 Second, don't be distracted from the ongoing
17 proceedings by your note taking. Overindulgence in note
18 taking is unreasonable and it's distracting. As jurors, it's
19 your duty to assess the credibility of the witnesses who
20 testify before you. In order to assess each witness's
21 credibility, you must observe the demeanor and the appearance
22 of each witness on the witness stand as the witness is
23 testifying. Note taking must not distract you from that
24 task. If you want to make a note about something you've
25 heard, you don't need to sacrifice the opportunity to make

1 important observations about the witness first. You may make
2 your notes after making those important observations.

3 Keep in mind that when you ultimately make a
4 decision in this case you will rely principally on your eyes,
5 your ears and your mind, not your fingers or your notes.

6 Third and last rule. Do not use your notes as
7 authority to persuade other jurors. The fact that it's in
8 your notes doesn't mean it happened. It means it's how you
9 perceived the testimony and the exhibits. Your notes should
10 be used only as aides to your own memory and may not be used
11 as authority to persuade your fellow jurors of what the
12 evidence was during the trial. You might make an error or a
13 mistake in recording what you've seen or heard. In the end,
14 each juror must rely on his or her own recollection or
15 impression as to what the evidence was. Your notes are not
16 official transcripts of the testimony.

17 With these limitations, you are granted permission
18 to take notes. At the end of each day, during any breaks
19 during the day, please place your notes in the envelope which
20 has been provided. This envelope will be taken and secured
21 each night. No one will be reading your notes or having
22 access to them. The envelope will be returned to you at the
23 beginning of each day. At the conclusion of the case after
24 you have used your notes in your deliberations, they will be
25 collected and they will be destroyed. Nobody will see them.

1 No one will violate the secrecy of your deliberations.

2 If you choose not to take notes, remember it is
3 your individual responsibility to listen carefully to the
4 evidence. You cannot give this responsibility to someone who
5 is taking notes. We depend on the judgment of all members of
6 the jury. You must remember the evidence in the case.

7 That's the end of my preliminary instructions.
8 They will be more detailed at the end of the trial, but
9 that's to help you have some context for what you're about to
10 see and hear.

11 Any reason to approach, counsel?

12 MR. AFRAME: No, your Honor.

13 MR. RICHARD: No, your Honor.

14 THE COURT: All right. What you're going to hear
15 now are the opening statements. Just to remind you, opening
16 statements are not evidence. Evidence is testimony,
17 exhibits, and sometimes what we call stipulations, if they
18 make an agreement. Sometimes they do, and if they do make an
19 agreement you may consider that to be proven, but we'll see
20 if that happens during the trial. The important point now is
21 these are opening statements, they're not evidence, they're
22 just a preview of what the attorneys think the evidence will
23 be. Who is opening for the prosecution?

24 MR. AFRAME: I am, your Honor.

25 THE COURT: Are you prepared?

1 MR. AFRAME: I am.

2 THE COURT: Please proceed.

3 MR. AFRAME: Good morning, members of the jury.
4 When a medical provider sees a patient they have one
5 obligation, and that obligation is to look out for that
6 patient's best interests. This case is about a violation of
7 that obligation, a violation fueled by financial greed.

8 Over the next several days you're going to learn
9 about the defendant, Christopher Clough. He was a
10 physician's assistant working at a PainCare clinic in
11 Somersworth, New Hampshire. And you are going to learn that
12 over a year period approximately from June of 2013 to the
13 early fall of 2014 he prescribed several million dollars'
14 worth of Subsys, a fentanyl spray, and that while he was
15 doing that he was paid by the maker of that drug, a company
16 called Insys, almost \$50,000 in purported speaking fees. And
17 you are going to learn that for most of those occasions on
18 which he was paid \$50,000, there was no speaking. He just
19 had dinner at a nice restaurant in Boston or Portsmouth with
20 the sales rep from the company.

21 Let me just talk to you a little bit about what the
22 crime is. Judge Laplante explained that to you and I just
23 want to touch on it for a second.

24 The essence of what has to be proven here is that
25 the defendant received remuneration for prescribing a drug

1 paid for by a federal health care program. I just said a lot
2 of words, but a lot of them are not going to be in dispute, I
3 don't think. In fact, I know one of them is not going to be
4 because we have a stipulation. Judge Laplante just told you
5 about stipulations. And you're going to hear a stipulation
6 that the defendant during the relevant period of time wrote
7 \$2.1 million worth of Subsys that was paid for by Medicare.
8 Medicare is a federal health care program.

9 You will also -- you will also hear me use the word
10 remuneration, it simply means payment, and I don't think
11 there's going to be any dispute in this case that the
12 defendant received just short of \$50,000 from Insys and that
13 he prescribed a large amount of Insys -- of Subsys.

14 So that brings us to really what I think this trial
15 is going to be about. What effect did that payment of that
16 almost \$50,000 have on the prescribing practices of the
17 defendant. I think that's the real question here. And so
18 what I want to do with the remaining 20 minutes or so is talk
19 to you about what I think the evidence is going to be on that
20 critical point that you eventually are going to have to
21 decide.

22 The first witness you are going to hear is going to
23 talk to you some about the drug Subsys. Her name is Dr.
24 Sharon Hertz. She is the director of the part of the Food
25 and Drug Administration that handles pain medications. The

1 Food and Drug Administration is the government entity that
2 approves drugs for being sold in the marketplace. And she
3 will tell you that back in 2012, '11 and '12, she was the
4 deputy director of that part of the FDA and in that role she
5 oversaw the process by which Subsys was approved to be sold
6 on the market.

7 And she's going to talk to you a little bit about
8 how opioids work to fight pain, and she's going to describe
9 to you the pain medication fentanyl and its uses, and she's
10 going to describe for you that there are different kinds of
11 opioids, and she's going to tell you that fentanyl has been
12 around for a long time and it can't be taken as a pill.
13 Originally it could only be taken through an IV, through a
14 needle. Eventually a patch was developed. And then it was
15 discovered that fentanyl could be taken into the body through
16 the lining of the mouth. The skin in your mouth is thin, and
17 that area is called the transmucosal, a fancy word for a
18 region of the body, but it's just the inner part of the
19 mouth. And she's going to tell you that in the late 1990s it
20 was discovered that fentanyl could be absorbed into the body
21 through that method.

22 In between the late '90s and 2012 companies came up
23 with several different kinds of drugs that could be taken --
24 fentanyl drugs that could be taken through the mouth. One
25 was a lollipop. One's a lozenge. And you will learn that

1 what Subsys is is a spray, a little bottle like this, and you
2 would spray it under the tongue. And you're going to hear
3 the term sublingual, another big word. That just means under
4 the tongue.

5 And these drugs are all in a certain class.
6 There's an acronym you're going to hear bandied about the
7 courtroom called TIRF, T-I-R-F, transmucosal immediate
8 release fentanyl. In the mouth, immediate, it's going to
9 work immediately, release fentanyl. And she's going to tell
10 you that the FDA approved that drug for breakthrough pain in
11 cancer patients. She's also going to tell you several
12 serious risks that are associated with that drug, including
13 depressed breathing, potential for overdose, severe
14 potentially fatal causes if it gets into the hands of
15 children, and the risk of abuse and misuse and addiction.

16 She's going to tell you that these TIRF drugs are
17 supposed to be used with another opioid. So everyone who
18 gets a TIRF drug she's going to tell you should be taking
19 some other kind of opioid on a regular basis, like oxycodone
20 for example. And she's going to tell you that sometimes
21 patients may have what's called breakthrough pain, that
22 baseline level of pain medication isn't working and they have
23 a spike, and when that happens this kind of TIRF drug can be
24 used to help someone get some immediate relief from that
25 breakthrough pain that they might be suffering.

1 She's also going to tell you that the FDA has
2 certain authority to put special requirements on drugs that
3 pose substantial risks. Not all drugs have these, she's
4 going to tell you, but this drug, these TIRF drugs do.

5 I'm going to give you one more acronym and I
6 promise that's it. REMS, risk evaluation mitigation
7 strategy. So there's a program that the government mandates
8 for the prescribing of a TIRF drug called the TIRF REMS
9 program. So what does that require before a patient can
10 receive this drug? Well, it requires several things.

11 First, it requires that the prescriber enroll in
12 the program, actually sign a document saying I am going to be
13 a doctor or a prescriber who is going to give out these TIRF
14 drugs.

15 Then they have to take certain education -- review
16 certain education materials and take a test on which they
17 have to pass with a perfect score and retake that test every
18 two years.

19 Most importantly for this case, however, they have
20 to talk to the patient in a way that is mandated and more
21 extensive than is required for other drugs about the TIRF
22 drug that they are proposing to give that patient. There has
23 to be a medication guide, you'll see this document, that's
24 required that has to be given to the patient. The prescriber
25 has to go through with the patient before providing the drug

1 all of the risks that are associated with the drug, how to
2 use the drug, how to safely store the drug, and how to
3 dispose of the drug when done. And the patient has to sign
4 off on this discussion before the drug can be prescribed.

5 And what's the purpose of all of this? It is to
6 make sure that a patient is fully informed about this drug
7 and all the risks that are associated with it so that they
8 can make their own decision about whether this is something
9 they want to take if they are having breakthrough pain.

10 After Dr. Hertz, you will hear from a witness from
11 the Board of Medicine, and she will give you some background
12 into what is a physician's assistant. Some of you may have
13 seen a physician's assistant, some of you not. You will
14 learn that they need two years post college; that they are
15 licensed by the state; that they have to take an exam; that
16 they can prescribe medication and they can perform medical
17 procedures, but they must do so under the supervision of a
18 medical doctor.

19 And you will hear that witness also read some
20 testimony that the defendant gave at a different proceeding
21 in which he described, among other things, his practices for
22 prescribing opioid medications and his claims that he did so
23 in a very conservative manner.

24 After that witness you will hear from two employees
25 from Insys, Jeffrey Pearlman and Natalie Levine Babich, who

1 at the time was known as Natalie Levine. Before I talk about
2 what they're going to tell you, I want to tell you two things
3 that they have in common. They have both pled guilty in
4 another federal court in Connecticut to having been engaged
5 in paying kickbacks to doctors and other prescribers on
6 behalf of Insys through this speaker program that you're
7 going to learn about.

8 And you are going to hear that they are both
9 awaiting sentencing in their respective cases and that they
10 have both agreed to cooperate with the government and that
11 they are testifying in this case in the hope that they will
12 earn some leniency on the sentences that they are currently
13 facing.

14 Now, Mr. Pearlman is going to tell you that he came
15 to work at Insys a little after the product came on the
16 market. It had been on the market for a little under a year.
17 And he will tell you that when he came to work for the
18 company, Subsys was not doing very well. And he will tell
19 you that it faced certain impediments to becoming a popular
20 drug.

21 You will hear from Dr. Hertz, and Mr. Pearlman will
22 say it too, this is for breakthrough pain in cancer patients.
23 That's not a huge population. There are already many
24 different TIRF drugs in the marketplace. It was crowded.
25 It's a very expensive drug. You are going to hear testimony

1 that this drug cost somewhere between 10 and \$40,000 a month.
2 Insurance companies, not surprisingly, don't always want to
3 pay such fees and so they require what's called
4 preauthorization, meaning the doctor, the prescriber, has to
5 provide information to the insurance company before the drug
6 will be approved for the insurance company to pay.

7 And Mr. Pearlman will tell you that there's a lot
8 of paperwork, there's a lot of bureaucracy that goes along
9 with that. A lot of prescribers don't want to deal with
10 that. And he'll also -- and so he'll tell you that those
11 were some of the problems. And another problem was that
12 while you wait for prior authorization that patient has no
13 medication, they're waiting, and that's not good either.

14 So he'll tell you that sometime in 2012 Insys hired
15 a new director of sales. His name was Alec Burlakoff. He
16 hired Mr. Pearlman. They were friends from summer camp back
17 when they were both teenagers. And Mr. Pearlman will tell
18 you about how Insys changed its sales model once Mr.
19 Burlakoff would be hired. He's going to tell you that the
20 mantra of the Insys sales force was find your one prescriber.
21 Find your one doctor and live with that person. Spend as
22 much time with that one prescriber as humanly possible. Be
23 in their office every single day if you have to. And he will
24 tell you that the other part of the sales pitch was make that
25 one prescriber, make them a speaker in the Insys speaking

1 program. And he will tell you why that was. That way the
2 prescriber could have a financial stake in the writing of
3 Subsys.

4 The government is not going to ask you to rely just
5 on Mr. Pearlman for that. You are going to see e-mails
6 inside of Insys that make this abundantly clear. For
7 example, there will be an e-mail that will say from a sales
8 manager to sales reps, no scripts, no programs. You don't
9 write the drug, you're not going to speak.

10 Mr. Pearlman -- you will see a formal written
11 agreement that Mr. Clough signed that talks about what he's
12 going to do as a speaker and not surprisingly, that document
13 will say that he's not going to be influenced in any way by
14 what he gets as far as money from Insys, but Mr. Pearlman
15 will tell you about the verbal agreement that goes on between
16 Insys sales reps and the prescribers. No scripts, no
17 programs.

18 And Mr. Pearlman will tell you that he hired
19 Natalie Levine sometime in 2013 to be a sales rep and she was
20 assigned to New Hampshire, and at first she couldn't find
21 that one prescriber. He'll say she appeared to be a bust.
22 But at the end of June 2013 she found the defendant. She
23 found her one prescriber. And he went from not having
24 prescribed this drug at all to being one of the most prolific
25 writers of this drug in the country.

1 And she will tell you that almost immediately she
2 did the second thing you're supposed to do under the Insys
3 sales model, ask the person to be a speaker. And you will
4 see that in early/middle July the defendant submitted his
5 resume to be in the Insys speaker program. That's July 15th.

6 You will see an e-mail from August 2nd, two weeks
7 later, in which -- it's from Alec Burlakoff, the head of
8 sales for Insys, reporting to Mr. Pearlman about a
9 conversation with the defendant. His description of the
10 defendant's excitement was that his excitement was coming
11 through the phone and that Mr. Pearlman should make sure that
12 they find some extra speaking opportunities for the
13 defendant.

14 And then you'll see on the very next day, August
15 3rd, an e-mail from the defendant to people working in Insys
16 handling the logistics for the speaker program. What's the
17 one question he asks? What's the fair market rate for what
18 I'm going to be doing? What am I going to get paid?

19 And Natalie will tell you that she wasn't adverse
20 to getting people to attend these speaking events, and in
21 fact she tried in the beginning to get people, but nobody
22 wanted -- no doctor wanted to come hear a physician's
23 assistant talk about a drug for breakthrough cancer pain.
24 And so she will tell you most of the time she couldn't get
25 anyone to come, but she also knew that the one thing you

1 don't do is cancel a speaking event because that money had
2 already been promised to the doctor.

3 And she will tell you that in about this year
4 period there were between 35 and 40 dinners that the
5 defendant attended, and he received a thousand dollars a
6 shot. And she will tell you that before each dinner, before
7 he set out to either Portsmouth or Boston, you'll see the
8 various restaurants, that he would call her and ask whether
9 anyone was going to be there, whether he would have to do
10 anything. And she'll tell you every once in a while maybe
11 there was someone else there but most of the time there
12 wasn't, and it was either a dinner in which it was she and he
13 alone, sometimes she brought a friend, one time the
14 defendant's children came, but there was no speaking going
15 on. And that happened time and time again.

16 Now, Insys required some paperwork you'll hear
17 before they'd issue the check. It's a company and they had
18 forms that had to be done, including rules about who needed
19 to attend, and that two people who worked in the medical
20 field were supposed to be there and most of the time they
21 weren't.

22 So you will hear from Natalie Levine that the
23 defendant would provide names, they would fill out this form,
24 and often the defendant would sign these people's names,
25 other people that he worked with at his pain clinic, but they

1 weren't at the dinners.

2 And this was profitable. No question. Insys made
3 millions of dollars. Natalie Levine made several hundred
4 thousands of dollars on the defendant becoming one of the
5 biggest writers of Subsys in the country. And the defendant
6 himself, as I've already said you'll hear, made almost
7 \$50,000 in a year's time for using his script writing to
8 write all of this Subsys.

9 And you will hear from FBI analysts who have
10 examined the thousands and thousands of pages in this case,
11 and they will present to you a few points. One, the
12 defendant during that year period wrote about 774
13 prescriptions of this drug and he attempted to write it for
14 138 unique patients.

15 You will hear that during that time Insys wrote him
16 a whole series of checks for his purported speaking programs
17 and that he deposited all of those checks into bank accounts
18 that he controlled. And you will see a chart that shows the
19 more scripts, the more programs. As the scripts eventually
20 came down, so did the programs. No scripts, no programs.

21 And you will hear from the defendant's supervisory
22 physician. Remember I told you that a PA has to have a
23 supervisory physician? You will hear from Dr. Schermerhorn
24 who supervised the defendant in 2013 and 2014, the relevant
25 period, and he will tell you that he did not know that the

1 defendant was attempting to write this very potent drug for
2 138 unique patients.

3 And he'll tell you that he only found out about it
4 when the defendant was out of the office and a medical
5 assistant came in one day and said, hey, Dr. Schermerhorn,
6 can you sign, can you sign this script for the defendant?
7 And Dr. Schermerhorn said that he was quite surprised and
8 disturbed that this was a 400 microgram dose of Subsys and he
9 questioned the defendant about that, and what the defendant
10 didn't say at that time was he had a whole bunch of patients
11 on 1200 and 1600 microgram doses of this drug.

12 So he didn't tell -- you will hear he didn't tell
13 his supervisory physician anything about this medical
14 discovery that he apparently made at the end of June 2013.

15 And you will hear from several witnesses whose
16 names were signed as coming to those speaking events, all the
17 people who worked at PainCare, and they're going to tell you
18 we didn't go to those events, we didn't sign our names, and
19 we didn't tell anyone that they could sign those names on our
20 behalf.

21 And you will hear from several of the patients that
22 the defendant treated. And these are people -- don't get me
23 wrong, these people do all suffer pain, and you're going to
24 hear some pretty sad stories about what has happened to them.
25 And their stories are all different, but they do have a

1 couple of things in common that are important.

2 One is, remember I told you at the beginning that
3 the defendant is supposed to make certain detailed
4 disclosures about the risks of the drug, how to take the
5 drug, how to store the drug, how to dispose of the drug so
6 someone can decide whether this is a drug they want to take?
7 All these patients are going to say that did not happen. And
8 they are also going to tell you the defendant never told them
9 that he was getting paid by Insys at the time that he was
10 telling them Subsys was the answer for them.

11 And you're going to hear one patient who is going
12 to tell you about the effects this drug had on him and that
13 it became -- he was falling asleep at the dinner table, he
14 was withdrawing from regular family activities, and that his
15 wife was concerned about what this drug was doing to him.
16 And she went to the appointment with her husband to tell the
17 defendant this drug was having a bad effect on him, and Mr.
18 Clough said -- called the husband a baby, dismissed the wife,
19 said to the husband, we'll take care of this, and he did
20 nothing. He kept him on the drug.

21 Finally, you will hear that in December of 2016 the
22 investigation against Insys had been ongoing but was not yet
23 public, and the FBI decided before it became public to knock
24 on Mr. Clough's door and see if he would agree to an
25 interview and he did.

1 He said a couple of things that I think are of
2 note. You will hear from an FBI agent who conducted the
3 interview. She'll tell you that he claimed to have trouble
4 remembering Natalie Levine's name. He had had dinner with
5 her 35 or 40 times at a whole bunch of nice restaurants over
6 a year-long period, and when the FBI came to ask questions,
7 he had trouble remembering her name. And when he did
8 remember her name, he said, my relationship with her was no
9 different than any other drug rep that was in and out of
10 PainCare. There was nothing special about my relationship
11 with Natalie Levine or Insys. It was all just the same.

12 And he'll say that he didn't sign anyone else's
13 name to those sign-in sheets. In fact, he is quoted as
14 saying, why would I do that?

15 The defendant had an obligation to look out for his
16 patients' best interests. After you hear all the evidence my
17 colleague, Charlie Rombeau, will come back before you to
18 argue to you that the evidence in this case proves beyond a
19 reasonable doubt that the defendant didn't do so. Rather, he
20 succumbed to his own greed and in doing so, ladies and
21 gentlemen, he violated the law.

22 Thank you.

23 THE COURT: Is the defendant going to give an
24 opening statement?

25 MR. RICHARD: Yes, your Honor, I will be.

1 THE COURT: Please proceed.

2 MR. RICHARD: Thank you.

3 Good morning, ladies and gentlemen.

4 Once again, my name is Patrick Richard. I'm here
5 with Robin Gagne on behalf of Mr. Clough.

6 Now, the government told you that this case was
7 about greed, individual greed. I suggest to you all that
8 this isn't a case about individual greed but a case of
9 corporate greed.

10 Mr. Clough up until 2015 was a physician's
11 assistant at a place called PainCare. As you can tell by the
12 name, it's a place where people's pain is treated by
13 physicians and doctors and physician's assistants, nurses,
14 and anybody else that works at that clinic.

15 Now, up until 2015 Mr. Clough was treating patients
16 there who were all in pain. Now, he treated them through
17 counseling them, speaking with them, ordering massages for
18 them to help relieve their pain, giving them physical
19 therapy, giving them injections, and even giving them
20 prescriptions.

21 Part of those prescriptions were pain meds, opioid
22 drugs. One of those drugs ended up being Subsys that he
23 regularly gave prescriptions to his patients.

24 Now, when you work -- you'll find I think when the
25 testimony comes out throughout the trial here, throughout

1 this week and throughout next week, you will hear that sales
2 reps would call on doctors and physician's assistants at
3 these clinics and try to make sales of their drugs.

4 Essentially they would come in and try to woo the doctors and
5 woo the physician's assistants, anybody that could write a
6 script, to say ours is better than theirs. Essentially one
7 company would come and say our company is better at treating
8 the pain than their drug.

9 One of those that came in, and Mr. Clough found out
10 in 2013, was Insys. Insys was a company that was fairly new.
11 Their drug was fairly new. Their drug was Subsys. As Mr.
12 Aframe told you, this was a drug that was taken sublingually,
13 taken underneath the tongue.

14 And I think the testimony you're going to hear is
15 going to tell you that the reason why they were pushing this
16 a little more than the other drugs is because they thought it
17 worked better. How did it work better? Well, the other
18 drugs, as Mr. Aframe told you, one was like a lollipop that
19 you would put in your mouth. But as we all remember from
20 when we were kids eating Tootsie Pops, you put it in your
21 mouth, one lick, two licks, and then you bite it. Well, when
22 you bit the lollipop, it didn't work as well.

23 This drug will go straight into your system
24 underneath your tongue. It was this little tiny device, this
25 little piece here, you would spray it once under your tongue

1 and that was it. The entire amount of drug would go into
2 your system. Nothing was wasted. Nothing was sent to your
3 stomach. It all went straight into your system to help treat
4 the pain.

5 And you will find out in the testimony here that it
6 treated pain faster. Instead of waiting 20 minutes, 30
7 minutes, an hour for it to work, it would work between five
8 and 20 minutes.

9 Now, the sales representative essentially from
10 Insys was Natalie Levine. She's now Natalie Babich or
11 Natalie Levine Babich. She'll testify and she will tell you
12 about how she pushed this drug to Mr. Clough; that
13 essentially she met him, showed him how it worked, and then
14 they met for dinner. And throughout their meeting he learned
15 how well this drug worked. He talked to some of his patients
16 who were already on it. There was another doctor at the
17 clinic named Dr. Greenspan, he had actually left the clinic.
18 But he was taking over his patients, and he learned from one
19 of these patients that this really worked for him. It
20 changed his life. It made life easier for him to deal with
21 the pain.

22 And this isn't regular pain that we all deal with.
23 You know, we hurt our elbow, we hurt our arm, we wake up with
24 a stiff neck. This is pain -- people have long-term chronic
25 pain for years. They're under treatment for chronic pain.

1 So some of them really need something to work.

2 As Mr. Aframe told us, there's your baseline pain
3 and sometimes there's a spike. Essentially it shoots up and
4 suddenly you're in pain. The medication you took that
5 morning doesn't work. You need to take something. That's
6 where Subsys would come up and you would take that and it
7 would work for you.

8 You will hear evidence to show that Mr. Clough
9 tried this with some patients, realized it worked. He was
10 excited about it. As Mr. Burlakoff's e-mail that you will
11 see said, he was enthused about this. He was excited about
12 this. Mr. Burlakoff was excited that somebody was excited to
13 sell his drug, so Natalie asked him to be a speaker.

14 Now, this is a way that pharmaceutical companies
15 push their drugs. They get somebody who is a regular
16 prescriber of this medication to speak to other doctors. Why
17 are you enthused about it, what does it do for your patients,
18 and they want somebody with experience to tell the other
19 doctors why this works and how this works. So I suggest to
20 you that's why initially Mr. Clough was asked to do this.

21 Now, one thing I think will come out through this
22 trial is that Mr. Clough didn't know Insys's dirty little
23 secret, and that's that they were greedy. They wanted money
24 bad. They were in a private market, as Mr. Aframe said, they
25 wanted to sell pain treatment drugs, and that they would do

1 anything now to sell it. And under Mr. Burlakoff's tutelage
2 as the now marketing supervisor at Insys, they were now going
3 to try to pay doctors to prescribe.

4 Now, the issue is, of course, did Mr. Clough know
5 about this. Was he told if you write more scripts we're
6 going to pay you more money? I suggest, ladies and
7 gentlemen, that that discussion was never had; that Mr.
8 Clough was actually excited about this drug; that Mr. Clough
9 felt it would help his patients; that Mr. Clough realized at
10 no point that he was doing this to get a kickback, to get a
11 bribe. He was doing the prescriptions simply for the reason
12 that he was helping his clients, his patients.

13 He was asked to speak. He was excited about this.
14 He learned about the drug. He learned how to talk about the
15 drug. And there weren't only dinners, but there were also
16 lunch meetings. They were done at his clinic. Not only done
17 with people who worked at his clinic but people who worked
18 from other clinics -- they're owned by the same person by the
19 way -- that would come in for lunch. They would have lunch,
20 they would be fed, but he would also talk to them about the
21 drug and he would tell them what luck he had.

22 Now, he would not only talk to the physician's
23 assistants and the doctors, he would also talk to office
24 staff so that they who had contact with the patients could
25 tell them what this drug did, what it was about and how it

1 will work, that everybody in the office then would become
2 familiar how to use this drug.

3 Now, there were a large number of events, probably
4 about 40 plus events. And at most of those events people did
5 show up and he did talk about Subsys. Now, there were other
6 events where people didn't show. Where Natalie Levine, I
7 would suggest to you, ladies and gentlemen, and you'll hear
8 from the testimony that she gives and other people give on
9 the stand, I think she got lazy. I would suggest to you she
10 was lazy; that she said he's already writing scripts, why do
11 I have to try and get people here? It doesn't matter.

12 So at about seven or so events absolutely nobody
13 showed up. It was essentially her, maybe her assistant, and
14 Mr. Clough.

15 Mr. Clough still got paid for two reasons. One,
16 Mr. Clough had a contract with them. If he showed up at an
17 event, they had to pay him. That's what Mr. Clough knew
18 about I would suggest to you, ladies and gentlemen.

19 Something he didn't know about, as I told you
20 earlier, was the greed, the greed of Insys, their MO, their
21 policies. Pay these doctors to show up. Get them to be
22 happy. Pay them to write these scripts. I would suggest to
23 you, ladies and gentlemen, Mr. Clough didn't know that. The
24 government has to show you that Mr. Clough knew what was
25 going on here; that Mr. Clough was aware that they're paying

1 him to write scripts.

2 I would suggest to you, ladies and gentlemen, from
3 the testimony you're going to hear throughout this trial this
4 week and next week that Mr. Clough actually was a physician's
5 assistant who cared about his patients, who wanted them to be
6 pain-free or at least to relieve their pain. A lot of
7 people, as we know, can't be pain-free, and we'll hear
8 testimony regarding that. Some of these patients couldn't be
9 pain-free, but he wanted to at least relieve their pain. Or
10 did he do this out of greed? I would suggest to you that Mr.
11 Clough did not do this out of greed. He did this to help his
12 patients.

13 The government has to show you that he did this to
14 get a kickback, that he did the prescribing to get a bribe,
15 to get money. I suggest to you, ladies and gentlemen, keep
16 an open mind. You will hear a lot of testimony over the next
17 two weeks. Mr. Clough did this to help his patients, not to
18 get money or bribes. I suggest when you hear all of the
19 testimony that the government will present to you, you will
20 not be able to come back and say that he's guilty, and in
21 fact you will come back with a verdict of not guilty. There
22 was no agreement with other parties to get kickbacks. He did
23 not receive kickbacks.

24 Thank you very much for your time in this matter.
25 I look forward to speaking to you at the very end of this and

1 again reminding you of what all the evidence is, and I would
2 suggest that again you will be able to come back with a
3 finding of not guilty. Thank you.

4 Thank you, your Honor.

5 THE COURT: Thank you, counsel.

6 All right. You've heard the opening statements.
7 Now we'll begin with evidence. The prosecution will begin
8 calling witnesses in support of its case. You probably want
9 to move that podium to a spot you would like to use.

10 MR. AFRAME: The government calls Dr. Sharon Hertz.

11 THE COURT: Dr. Sharon Hertz.

12 DR. SHARON HERTZ

13 having been duly sworn, testified as follows:

14 THE CLERK: For the record, please state your name
15 and spell your last name.

16 THE WITNESS: Sharon Heidi Hertz, H-E-R-T-Z.

17 THE CLERK: Thank you. Please be seated.

18 DIRECT EXAMINATION

19 BY MR. AFRAME:

20 Q. Good morning, Dr. Hertz.

21 A. Good morning.

22 Q. Could you first tell us where do you currently
23 work?

24 A. I currently work for the Food and Drug
25 Administration.

1 Q. And I'm going to come back and ask you a lot of
2 questions about that work, so why don't I ask some additional
3 background and then we'll come back to that.

4 So you are a medical doctor?

5 A. Yes.

6 Q. And where did you go to medical school?

7 A. I went to medical school at Health Science Center
8 at New York, part of the state University of New York system.

9 Q. And after medical school, can you just tell us a
10 little bit about your post-medical school training?

11 A. I did residency at Downstate Medical Center in
12 Brooklyn, SUNY Health Science Center in Brooklyn, and that
13 was a neurology residency followed by a fellowship.

14 And then I was in practice for a little bit, took
15 another fellowship and stayed on at Downstate as an attending
16 physician, and then I took a practice position at a hospital.

17 Q. And what kind of medicine did you practice before
18 joining the FDA?

19 A. Neurology with a specialty in epilepsy or seizures,
20 but I also did pain management as part of my general
21 practice.

22 Q. And when did you join the FDA?

23 A. In 1999.

24 Q. And what is your current job at the FDA?

25 A. I am currently director for the division of

1 anesthesia, analgesia and addiction products. It's a review
2 division in the Center for Drug Evaluation and Research.

3 Q. And you said anesthesia. So what's that?

4 A. So anesthesia are all the medicines used in the
5 operating room to help put patients to sleep and to manage
6 pain and other situations.

7 Q. And analgesia?

8 A. Analgesia is pain medicine, all medicines used to
9 treat pain. And addiction medicine is medications to treat
10 all forms of addiction, whether it's for opioids or nicotine
11 or alcohol.

12 Q. And you said right now you're the director of this
13 part of the FDA?

14 A. Yes.

15 Q. And back in 2011 and '12, what were you?

16 A. I was deputy director for the same division in
17 charge of the pain products.

18 Q. And tell me, what does your division do?

19 A. So we have regulatory oversight of pharmaceutical
20 companies. When they want to develop a drug, they come to us
21 before they can start testing the drugs in humans and we
22 review the protocols to make sure they're safe. And then
23 when they're ready to come to market, we review all of the
24 information they've acquired through studies and we make a
25 decision about whether or not the benefits of the product

1 outweigh the risks and if it should come to market.

2 Q. And how, just briefly, I'm sure it's an involved
3 process, but generally how do you go about doing all of this?

4 A. Well, the companies are required to submit all of
5 the information that they've acquired in doing studies. So
6 any studies in the U.S., any studies in other countries, and
7 any relevant literature, any articles or scientific articles
8 that have been published have to be submitted to us. We
9 review the actual data. We reanalyze the data with our own
10 statisticians, and we have a team that includes physicians,
11 chemists, clinical pharmacologists, animal pharmacologists so
12 that we can review all the information.

13 Q. And was Subsys a drug that went through this
14 process?

15 A. Yes.

16 Q. And what was -- and when was that process ongoing?

17 A. Well, we finished the approval in 2012 and I think
18 that was a year-long review process.

19 Q. What was your role in the review process for
20 Subsys?

21 A. So I wrote what's called the cross-discipline team
22 leader memo. It just is the memo that puts together all of
23 the information from all of those other specialists, the
24 chemists, the pharmacologists, all those people, the clinical
25 reviewer, into a large summary document that then goes to the

1 director who makes the final decision.

2 Q. And through that process did you become familiar
3 with Subsys?

4 A. Yes, very much so.

5 Q. And ultimately did the director approve Subsys to
6 be released into the market?

7 A. Yes.

8 Q. And when did that happen?

9 A. I think that -- I think that was April 2012. I'm
10 somehow blanking on the month.

11 Q. Was it in early 2012?

12 A. Yes.

13 Q. So let me step back and just ask you a few
14 questions about pain medications and how they work before we
15 get into Subsys itself.

16 Can you -- we've already -- what kind of drug in
17 terms of a broad class is Subsys?

18 A. So Subsys contains fentanyl. Fentanyl is what we
19 call a potent opioid.

20 Q. Let me stop you there. What's a -- so the broadest
21 class, is it fair to say that's opioids?

22 A. Yes.

23 Q. What are opioids?

24 A. Opioids are medicines that -- well, for a pain
25 medicine they're what we call mu opioids. They attach to a

1 very specific receptor on cells in the brain and other parts
2 of the body and they work through that mechanism. So they
3 work primarily on the brain and some other areas.

4 Q. And just briefly, how do they affect pain?

5 A. Well, they reduce the perception of pain so that
6 it's not -- patients don't feel it as severely. They reduce
7 that perception.

8 Q. And are there different kinds of opioids?

9 A. Yes. One of the big -- one of the categories would
10 be whether it's a synthetic opioid or a non-synthetic opioid.

11 Q. Is a natural opioid another way to describe that?

12 A. Yes.

13 Q. Let's talk about natural opioids first. Can you
14 give us some examples of what are common natural opioids that
15 are used?

16 A. So generally those are opioids that are derived
17 from poppies, from the chemicals in poppies. So morphine is
18 the most common one used that's a pain medication.

19 Q. Are there other ones that are commonly used?

20 A. Yeah, codeine and others. There's some that are
21 derivatives of that further, like oxycodone or oxymorphone,
22 hydromorphone.

23 Q. And so those are the natural opioids. What are the
24 synthetic opioids?

25 A. So that's the family of fentanyl, and it's

1 fentanyl, alfentanil, sufentanil, and remifentanil.

2 Q. And can -- so let's just take oxycodone which you
3 put on the natural side.

4 A. Semi-synthetic, yeah.

5 Q. How does one typically take oxycodone, what form?

6 A. It's usually a tablet taken by mouth, swallowed.

7 Q. And can the fentanyl be taken in the same way?

8 A. No.

9 Q. Why not?

10 A. Fentanyl -- when you take fentanyl by mouth, it's
11 exposed to different enzymes or chemicals in the stomach and
12 in the blood when it gets absorbed from the stomach, and they
13 break it down very quickly. It's called first-pass effect.
14 So fentanyl has traditionally been given by other routes that
15 get it into the blood.

16 Q. So has fentanyl been a drug that's been available
17 and known about for a long time?

18 A. Yes.

19 Q. When would you estimate sort of medicine started to
20 use fentanyl as a product to help with pain and anesthesia
21 related matters?

22 A. Well, it's been used as part of anesthesia for
23 decades.

24 Q. And initially what was the only way that a person
25 could take in the fentanyl?

1 A. It was given by intravenous administration into the
2 vein.

3 Q. And eventually was it discovered that fentanyl
4 could be taken into the body in ways other than
5 intravenously?

6 A. Yes. Next it became available as a patch, absorbed
7 through the skin, and then the transmucosal immediate release
8 fentanyl products were developed.

9 Q. And I promised the jury this. So what does
10 transmucosal mean?

11 A. So the inside of the cheek is what we call a
12 mucosal membrane, also the inside of the nose and other
13 parts. For fentanyl, if you put it on the inside of the
14 mouth it can be absorbed into the blood that way, and that
15 way it avoids what we call that first-pass effect when it's
16 absorbed through the stomach.

17 Q. And when was that idea that fentanyl could be taken
18 in through the mouth, when was that discovered?

19 A. The first transmucosal fentanyl was in the mid
20 1990s.

21 Q. I'm going to ask you more about that in a second.

22 I think you've already told us that the benefits --
23 you told us the FDA is interested in benefits and costs,
24 right?

25 A. Risks, yeah.

1 Q. And the benefits of these various opioids, both
2 natural and synthetic, are that they help with pain; is that
3 right?

4 A. Yes.

5 Q. What are the risks? What are the major risks that
6 are associated with these opioid medications?

7 A. Respiratory depression, meaning it slows breathing,
8 and it can slow breathing to the point of stopping breathing
9 which causes death.

10 It is very sedating. That's often in combination
11 with the respiratory depression, so that combination is the
12 most dangerous in terms of what's involved in a fatal
13 overdose, and of course they're addictive. They can cause
14 addiction.

15 Q. Just briefly, why is that?

16 A. Why is that?

17 Q. Do we understand why they cause addiction?

18 A. Yes, to some extent. So addictive medicines have
19 some property that makes them reinforcing, meaning you want
20 to take it again, and that combined with a physical change, a
21 physical tolerance, that combination supports addiction.

22 Q. Now, you told us already that this discovery that
23 fentanyl could be taken through the mouth was discovered in
24 the late 1990s. Based on your work at the FDA, are you
25 familiar with the first of the drugs that came on the market

1 that could be taken through the mouth?

2 A. Yes. It's called Actiq.

3 Q. Actiq. And how would someone take Actiq?

4 A. Actiq is a lozenge on a stick, and it's rubbed in
5 the space between the gum and the cheek until it dissolves
6 and the fentanyl is absorbed across the mucosa.

7 Q. And were there after that other kinds of
8 transmucosal fentanyl drugs?

9 A. Yes. The next one was a small tablet that
10 effervesced, it bubbles, and you put it between the gum and
11 the cheek and it would be absorbed that way. There were some
12 that were absorbed under the tongue. Different types of --
13 one was a small round patch that stuck to the inside of the
14 cheek. Just different ways to deliver the fentanyl to that
15 part of the mouth.

16 Q. Does the FDA have an acronym that describes this
17 entire class of drugs?

18 A. Yes. We call them the TIRF drugs, transmucosal
19 immediate release fentanyl.

20 Q. So it's T-I-R-F?

21 A. Yes.

22 Q. Let's talk about what they are approved for. What
23 did the -- does the FDA when it approved the drug decide what
24 it's going to be approved for?

25 A. Yes, we do, and that's based on the clinical

1 studies of the drug. The TIRF products are approved for
2 breakthrough pain in cancer patients on around-the-clock
3 opioid therapy and who are opioid tolerant.

4 Q. So you said I think four different things there and
5 I want to break that down.

6 So let me just make sure I've got the four right.
7 Breakthrough pain; is that right?

8 A. Yes.

9 Q. Cancer patients; is that right?

10 A. Yes.

11 Q. Opioid tolerant?

12 A. Yes.

13 Q. And around-the-clock opioid medication at the time?

14 A. Yes.

15 Q. All right. So first of all, can you tell me --
16 describe for the jury what do we mean when we say
17 breakthrough pain?

18 A. So in cancer patients in particular who have pain,
19 sometimes there are sharp increases in the pain, spikes in
20 the pain that can be very quick starting and typically don't
21 last very long. So those are breakthrough pain.

22 Q. And why does the FDA think that the benefits of --
23 and by the way, I guess I should have clarified this. Subsys
24 is one of these TIRF drugs, right?

25 A. Yes.

1 Q. Let me just make sure before we get back to
2 breakthrough pain, Subsys is taken through the mouth?

3 A. Yes, it's sprayed under the tongue.

4 Q. Are you familiar with this little thing?

5 A. Yes.

6 Q. And what is this?

7 A. That is the actual device that's held and sprayed
8 under the tongue.

9 Q. And this has been, just for the record, marked as
10 Government's Exhibit 160.

11 Do you know, from when you did the review, can you
12 just show, not really demonstrate it but what one would do?

13 A. So here's where the drug comes out, and you just
14 put your fingers around it and you open your mouth, lift your
15 tongue and spray it.

16 Q. Thank you. Now, you said that's good for
17 breakthrough pain?

18 A. Yes.

19 Q. Which is short-acting; is that right? Short --

20 A. It's typically short bursts.

21 Q. And so why is this a good drug for that? What's
22 the benefit?

23 A. Well, because it's absorbed directly into the
24 blood, it gets in a bit faster than if you swallow it and it
25 can work somewhat faster than taking a pill.

1 So when you have a quick burst of pain, you want
2 something to get in quickly to lessen that pain, but you
3 don't necessarily need it to last very long.

4 Q. And let me ask you -- let me skip down to No. 4
5 because I want to ask you a question that relates to those
6 two together and then I'll do the other two.

7 You said a person also needs to be on
8 around-the-clock opioid medications when they're taking
9 Subsys.

10 A. Yes.

11 Q. Or another TIRF drug. Why is that?

12 A. Fentanyl is very potent and to avoid serious side
13 effects of respiratory depression and sedation, it's
14 important for people to be opioid tolerant. Those two are
15 sort of together, opioid tolerant and around-the-clock
16 medicine. So if somebody is taking an opioid regularly
17 around-the-clock for at least a week or longer, the body
18 adjusts to some extent to the side effects and there's less
19 risk for reduced breathing, respiratory depression and
20 sedation. The body can adjust to that but the medication
21 still remains effective for treating pain.

22 Q. That around-the-clock opioid, is one taking that
23 just to make them ready to take fentanyl or does it have
24 another medical purpose other than that?

25 A. Absolutely not to be ready for fentanyl. The idea

1 of breakthrough pain is people have pain all the time and
2 then breakthrough pain is on top of that. It's different
3 from people who just have intermittent pain and no other
4 pain.

5 So these drugs were made specifically for people
6 who can't have their pain adequately treated with the
7 background medicine who need something extra for those
8 spikes.

9 Q. So let me ask about then how is one of these TIRF
10 drugs prescribed? So as I understand what you just told us,
11 someone is on around-the-clock, I'm just going to say
12 oxycodone as an example. Would that be right?

13 A. Correct.

14 Q. And then they have a spike and that's when you
15 would take the Subsys or the other TIRF drug?

16 A. Yes.

17 Q. And is that something that's prescribed to be taken
18 sort of every four hours or something or how does one know?
19 Is the TIRF drug taken on a regular basis or on an as-needed
20 basis?

21 A. It is only supposed to be used on an as-needed
22 basis, not to be on a regular schedule.

23 Q. And so when one is prescribed a TIRF prescription,
24 would you think that that would be for just a finite period
25 of time, or is it unclear how long it would take for someone

1 to go through that script?

2 A. It's variable how long it would take them to use up
3 the amount they were prescribed.

4 Q. And why is that?

5 A. Because it's only supposed to be taken when needed.
6 So only when those spikes happen.

7 Q. So we've talked about what breakthrough pain is and
8 I think you put opioid tolerant and around-the-clock
9 together.

10 So the last one is cancer patients. The FDA, am I
11 right to say, approved this for cancer patients?

12 A. Yes.

13 Q. Why?

14 A. Because that was the group of patients who had a
15 real need because of this thing called breakthrough pain.
16 There's a difference between pain that happens occasionally
17 and the pain that these patients were experiencing because of
18 the type of pain that comes with some kinds of cancer.

19 So it was a real need in the medical community to
20 find something that would help these people without having to
21 have them on a higher dose of opioid all the time. This way
22 the background medication could just treat the background
23 pain and they could use a little bit more when they needed
24 it.

25 Q. Now, is that a limitation -- is a prescriber only

1 allowed to prescribe under the law a TIRF drug for a cancer
2 patient?

3 A. No.

4 Q. Just tell the jury, why is that?

5 A. Physicians are allowed to use clinical judgment to
6 decide to use a medicine off-label, meaning something that
7 it's not specifically been tested and labeled for, if it's
8 safe and it fits the situation.

9 Q. And is that unique to this or is that just
10 generally how it works with all drugs?

11 A. That's generally how it works.

12 Q. Now, I want to talk a minute about how these drugs,
13 these TIRF drugs as far as dosing should be given to
14 patients. How does that work? What level of dose should a
15 patient start on in receiving one of these TIRF drugs?

16 A. In general, patients should always start on the
17 lowest dose. The first dose that they get should be the
18 lowest dose available. It's hard to predict how each patient
19 will react, so it's safest to start at the lowest dose in
20 most circumstances.

21 Q. Now, do you know from having done the Subsys review
22 what the lowest dose of Subsys was?

23 A. 100 micrograms.

24 Q. And so is it the FDA's recommendation that all
25 patients begin at 100 micrograms?

1 A. Yes. There's a small group of patients where that
2 isn't necessarily the case, but in general, yes, that's true.

3 Q. Okay. So you told us already that Subsys came on
4 the market sometime in early 2012. You've already showed it
5 to us and how it works.

6 What was unique about it?

7 A. It was the first spray for under the tongue
8 compared to tablets or that little sticky patch, but it was
9 only the way to get the fentanyl in that was different.

10 Q. In other words, was the drug -- the actual drug,
11 the active component in Subsys, any different than in the
12 other TIRF drugs?

13 A. No.

14 Q. Did the FDA make any conclusions about whether
15 Subsys was in some way superior to any of the other TIRF
16 drugs?

17 A. No.

18 Q. Do you know whether some TIRF drugs are available
19 in generic form?

20 A. Yes. Several are.

21 Q. Do you know which ones are?

22 A. I know that Actiq and Fentora are. There may be
23 some others. I'm not quite sure. I don't want to misspeak.

24 Q. Okay. That's fine. But you know some are?

25 A. Yeah. I think Abstral is.

1 Q. Okay. Let me ask you a little bit about how the
2 FDA goes about labeling a drug, and I want to bring up
3 Government's Exhibit 105 I think. Do you see that? It's
4 kind of small print, but we'll blow up the parts that we want
5 to talk about.

6 Do you see what's in front of you?

7 A. Yes.

8 Q. Do you recognize that?

9 A. Yes.

10 Q. What is that?

11 A. That's the first page of the labeling or package
12 insert for Subsys.

13 Q. And one drawback of our electronic evidence is we
14 don't know how long that document is, but it's many pages,
15 right?

16 A. Yeah, it's -- yeah, it's quite long.

17 Q. Okay. We're not going to go through the whole
18 thing, but I do want to talk about a few features of this
19 document. Now, tell us again where would one find this
20 really thick document that has lots of words and charts in
21 it?

22 A. So when -- it's typically printed and put in the
23 box of the product. It's also available online in a much --
24 so it's small and folded up, you may have seen those in the
25 package, and it's also available online and --

1 Q. And does every drug have a label?

2 A. Yes.

3 Q. And what's the -- does the FDA require the label?

4 A. Absolutely, yes.

5 Q. And why does the FDA do that?

6 A. Well, the label is how we communicate with
7 prescribers and patients what's important to know about the
8 drug.

9 Q. And if we went to the second page for a second, we
10 would see what looks to me like a table of contents. Is that
11 a table of contents?

12 A. Yes, that's for the full prescribing information.

13 Q. So what's the significance of the front page?

14 A. That's the highlights, and it's meant to be
15 condensed so that people can take a quick look and see the
16 most important information so that people don't necessarily
17 have to read the full, very long sometimes, longer document
18 if they just need a quick reference.

19 Q. So let's just look at some of the highlights. So
20 can you tell the jury what's a boxed label -- or a boxed
21 warning, excuse me.

22 A. A boxed warning is our strictest warning.

23 MR. AFRAME: Can you go back to the first page.

24 A. It is something that we use when we think just
25 including warnings in the label, typically they're in section

1 5, when we think that's not enough. The criteria are when
2 there's a serious adverse event, side effect that could --
3 that's very serious and that prescribers have to take into
4 consideration before prescribing the drug, and if there's an
5 adverse reaction that could be avoided with proper patient
6 selection or proper monitoring.

7 And it's also for when we have REMS, restricted --
8 in this case restricted access for a product, and that's a
9 risk evaluation and mitigation strategy.

10 Q. I'm going to actually ask you a lot of questions
11 about that in a minute, but right here have I blown up the
12 boxed warning?

13 A. Yes.

14 Q. So the last one talks about this TIRF REMS Access
15 program, and I want to ask more detail about that in a
16 minute. So let's put that one aside.

17 What are the other major risks that the FDA thought
18 required this special boxed warning attention?

19 A. As you can see, first and foremost is the risk for
20 respiratory depression. The nature of these medications and
21 the situations in which they are considered safe to use are
22 different than other opioids. So we wanted to highlight that
23 it's a very significant risk. And in particular, we
24 highlighted part of the indication that these medicines
25 should only be used in opioid -- should not ever be used in

1 opioid non-tolerant patients. And for managing more regular
2 pain like acute pain after surgery or headache, migraines,
3 this is not the right product.

4 Q. And it says it should be kept out of the reach of
5 children.

6 A. Yes.

7 Q. Why is that so important for this drug?

8 A. Because a single dose could be fatal in a child,
9 even the lowest dose.

10 Q. And the next one says: May cause fatal respiratory
11 depression?

12 A. Yeah, that's kind of a technical risk problem.
13 Some other medicines can reduce the body's ability to break
14 down fentanyl, and that's where that CYP3A4 inhibitor, that's
15 what that means. So if you're on a medicine that does that
16 kind of activity in the body, you have to be extremely
17 careful with anything that has fentanyl in it. Typically you
18 have to reduce the dose quite a bit if you're going to use it
19 at all.

20 Q. And it says: When prescribing, do not convert
21 patients on a microgram-to-microgram-basis from any other
22 oral transmucosal fentanyl product.

23 A. Yes.

24 Q. What does that mean?

25 A. That and the next one, what those mean are -- most

1 of these products come in strengths of 100 micrograms, 200
2 micrograms, 400. Some have additional strengths up to 800 or
3 more.

4 Because the body absorbs different medicines
5 differently even when they're in the same place, if you take
6 a 200 microgram Actiq dose, that may actually give you less
7 fentanyl than a 200 microgram Subsys. So if the doctor and
8 you decide as the patient that one medicine's not working,
9 you don't like the way it tastes or feels and you want to
10 change to another one, you can't simply say, okay, you're on
11 200 of this, I'll give you 200 of that. You have to start
12 again at the lower dose and see how that person, how their
13 body absorbs the medicine and how it makes them feel.

14 Q. And I just want to get the measurement straight.
15 I'm sure there will be some discussion about oxycodone in
16 this trial. Am I right to say that the way that we measure
17 oxycodone is in milligrams?

18 A. Yes.

19 Q. And here we're talking about micrograms?

20 A. Yes.

21 Q. Which is a smaller unit?

22 A. Much smaller. Fentanyl is roughly about 100 times
23 more potent than oxycodone or morphine.

24 Q. And so we're talking about smaller amounts?

25 A. Much smaller amounts.

1 Q. Okay. And the last boxed warning I want to talk
2 about is the one that says: Contains fentanyl, a Schedule II
3 controlled substance with abuse liability similar to other
4 opioid analgesics.

5 What is the FDA warning about there?

6 A. So we want to emphasize that opioid medication and
7 other medications are restricted in terms of how they can be
8 prescribed and that's based on the Controlled Substances Act,
9 which is something the DEA has developed, and there's
10 different schedules under that. Schedule I is something that
11 has no medical use, like heroin. Schedule II means there's a
12 medical use for the product, but it's also potentially very
13 addictive and very subject to abuse. So it's a way to -- and
14 there's different rules about how much and how often you can
15 prescribe Schedule II products to -- which is different than
16 products that have lower risk for abuse.

17 MR. AFRAME: And if we go down a little bit, can we
18 blow up the dosage and administration piece.

19 Q. What's this section, sort of the top page of the
20 label talking about?

21 A. So section 2 is dosage and administration, and it
22 gives the prescriber instructions how to prescribe the
23 medication safely, and it's based on the actual clinical
24 studies that are done that show how to use the product in the
25 safest way.

1 Q. And so the first one is: Must require use of
2 around-the-clock opioid. And you talked about that already,
3 right?

4 A. Yes.

5 Q. And the next one is the initial dose of Subsys is
6 100 micrograms?

7 A. Yes.

8 Q. And then it says: Individually titrate to a
9 tolerable dose.

10 What does the word titrate mean?

11 A. So titrate is how -- if a patient is not having an
12 adequate response to the 100 microgram dose, if it's not
13 having enough of an effect to lower their pain, you go up in
14 dose. So you titrate up in dose. And the goal of titration
15 is to balance enough pain relief with the side effects,
16 because the side effects are always going to be there. So
17 you want to have enough pain relief, but you don't want to
18 have too much sedation, and you definitely don't want to have
19 respiratory depression.

20 Q. And then there are three additional bullet points
21 there that talk about sort of limits on how much a person
22 should be taking at a time. Could you just tell us about
23 those?

24 A. Yes. If you take many doses of this, even though
25 it's expected to work for a limited period of time, it can

1 start to build up. So in testing it was found that in one
2 breakthrough pain episode if in the first 30 minutes it's
3 still not working, you can take another dose, but then you
4 have to wait four hours because we need the level of fentanyl
5 to start going down, the body to start breaking it down, and
6 then it's safe to use it again.

7 Q. Why is that? Why do we need to wait?

8 A. Well, if the fentanyl builds up, then it could
9 increase the risk of respiratory depression. Just because
10 somebody is opioid tolerant doesn't mean they're not subject
11 to the side effects. It just means they tolerate them
12 better. But if you take many doses and the levels increase,
13 then those problems can happen.

14 Q. And how many doses a day does it advise?

15 A. So it's limited to four or fewer doses per day. In
16 the full prescribing it also says that if you need more than
17 that, it's potentially because your background opioid isn't
18 strong enough and instead of taking more doses of Subsys, you
19 should talk to the doctor and the doctor may want to increase
20 the background medication instead. The background medication
21 doesn't have those highs and lows, it's more stable, so
22 people tend to tolerate that a little better.

23 Q. The last thing I want to talk about on this page
24 here are the contraindications. What does that word mean,
25 contraindication?

1 A. So a contraindication is a situation in which
2 because of the safety risks of a product there's no situation
3 in which we believe the benefits can outweigh those risks.
4 So it basically means the drug should never be used in that
5 setting.

6 Q. And the first one, which as I think we've already
7 talked about, is opioid non-tolerant patients?

8 A. Yes. There's three contraindications for this.
9 The first is it's not for use in opioid non-tolerant
10 patients.

11 Q. Next?

12 A. The next is that it's not to be used for acute
13 pain. So that's the use for, for instance, postoperative
14 pain or headaches or a backache, that type of thing, those
15 intermittent kinds of pains that basically you can manage
16 with other medicines.

17 Q. And the last one is intolerance to fentanyl, Subsys
18 or its components?

19 A. Yeah, so it's sort of like if you have an allergy
20 or if you're known to have very bad side effects from
21 fentanyl.

22 Q. Okay. So I skipped over one thing on this page,
23 which is back in the boxed label. I skipped over the last
24 piece there, the TIRF REMS Access program.

25 And actually, before I get to that, now that we

1 understand a lot of the risks that are associated with this
2 drug, let me ask you a couple of questions.

3 Should this drug be prescribed for a person with a
4 significant respiratory disease?

5 A. No.

6 Q. Why not?

7 A. Because the first thing that we worry about with an
8 opioid this potent is respiratory depression, and people who
9 have already existing significant lung problems are much more
10 susceptible, much more vulnerable to that respiratory
11 depression.

12 Q. Let me ask you this: Should a patient ever leave a
13 doctor's office having been prescribed two TIRF drugs at
14 once?

15 A. Two different ones?

16 Q. Yes.

17 A. No. Never.

18 Q. Why not?

19 A. Well, it's dangerous to double up on these.
20 There's a whole description in the dosage and administration
21 section on how to properly titrate one drug. And if the drug
22 is not adequate, then you don't add another one, you change
23 to something else and carefully titrate that drug. There's
24 no reason to be on two. There's many different ones to
25 choose from. So the goal is to find the right one for that

1 particular patient, not to just keep adding new ones on.

2 Q. And should these fentanyl drugs, should the plan of
3 the prescriber ever be to get to a point where they could
4 replace or reduce the around-the-clock opioid that the person
5 is on?

6 A. That's exactly opposite to how these should be
7 used. If the around-the-clock medicine is enough, then
8 there's no reason to prescribe these at all. These are only
9 meant to be in addition when the other kinds of medications
10 are not enough.

11 Q. So let me turn now to --

12 THE COURT: I think this is a good time to take the
13 morning break. We've been going about an hour and a half,
14 and I want to give the court reporter a break.

15 So we're going to take our first break in the
16 trial. You will be in the jury deliberation room. You can
17 take a bathroom break or whatever you need to do. Remember
18 to heed my instructions. You are free to talk socially but
19 no discussion about the trial during any of the breaks until
20 the evidence is completed. We are in recess.

21 (RECESS)

22 THE COURT: All right. Mr. Aframe, please
23 continue.

24 MR. AFRAME: Thank you, your Honor.

25 Q. So we were going through that boxed label earlier

1 in your testimony and I just omitted the last one and I said
2 I'd come back to it. So we've reached that point.

3 That says that Subsys is available through a
4 restricted program called the TIRF REMS Access program,
5 right?

6 A. Yes.

7 Q. And is that a requirement of the FDA?

8 A. Yes.

9 Q. Okay. I'm going to ask some questions about that.

10 MR. AFRAME: So if we could go to Government's
11 Exhibit 100 for a minute.

12 Q. This appears to be a letter on Department of Health
13 and Human Services letterhead, if we go to the first page.
14 Do you see that? And it says Food and Drug Administration.
15 Is this a letter from your agency?

16 A. Yes.

17 Q. Do you know what the purpose of this letter is?

18 A. This is where we inform the company that we've
19 approved a product.

20 Q. Okay. And can you tell by just looking at this
21 letter which drug we're talking about here?

22 A. Yes. It says Subsys in the third paragraph.

23 MR. AFRAME: Okay. So if we could just blow up
24 that third paragraph for a second.

25 Q. The new drug application provides for the use of

1 Subsys for the management of breakthrough pain in adult
2 cancer patients who are already receiving and who are
3 tolerant to around-the-clock opioid therapy for underlying
4 persistent cancer pain, and it says it's been approved,
5 right?

6 A. Yes.

7 Q. And we've gone through all of those indications
8 that I just talked about in that paragraph already, right?

9 A. Yes.

10 MR. AFRAME: So let's go to the next page, and
11 let's just blow up the bottom there that says risk evaluation
12 and mitigation strategy.

13 Q. There's a lot of legal looking stuff there, right?

14 A. Yes.

15 Q. Section 501-1 of the FDCA. What's the FDCA?

16 A. The Federal Drug and Cosmetic Act.

17 Q. Is that a statute passed by Congress?

18 A. Yes. That's what basically gives us our authority.

19 Q. Did Congress through a law give you some special
20 authority on how you can manage certain kinds of drugs?

21 A. Yes. Congress has given us the opportunity to use
22 these risk evaluation and mitigation strategies.

23 Q. And when did that come into the law?

24 A. 2007, and then we were ready to start actually
25 enacting them through regulation in 2009.

1 Q. And is the acronym for this REMS?

2 A. Yes.

3 Q. And not the Subsys TIRF REM yet, we'll get to that,
4 but in general what are the different ways the FDA sort of
5 goes about using its REM authority?

6 A. So we only use REMS or require a REMS when we think
7 that there is a safety concern that requires something more
8 than the usual information available in labeling or even some
9 of the patient labeling that goes in the label that's
10 connected to it.

11 Q. So we looked at the label already, right?

12 A. Yes.

13 Q. And we looked at the front page of the label that
14 had the boxed warning. So is it true that for many drugs
15 that's what the FDA requires as far as safety goes?

16 A. Yes, and many drugs don't have a boxed warning at
17 all.

18 Q. Okay. And so tell me what are the different kinds
19 of things the FDA has mandated under this authority that it
20 has for certain more dangerous drugs?

21 A. Well, REMS can cover a very broad spectrum. All
22 opioids currently now have a REMS but not as restrictive as
23 this. The general opioid REMS is trying to educate
24 prescribers and patients about risks and benefits and how to
25 use those products more safely through educational means.

1 For this, this is one of the more restrictive REMS,
2 and it actually requires that the patient and the prescriber
3 be enrolled in the program. The prescriber has to read the
4 educational material and take a test showing that they
5 understand the material, and they agree to a number of things
6 that are specified in the program. And then --

7 Q. Let me stop you there. We're going to go through
8 each of those in some detail, but let me just show you the
9 second page. I just want to get one of the purposes of the
10 REM. And now we're talking about this particular REM. And
11 what is the name of the particular REM that the FDA has
12 mandated for Subsys and the other drugs in its class?

13 A. So we call this the TIRF REMS Access program.

14 Q. If we go to the top paragraph of this third page of
15 the letter, it goes over from the prior page, but it says
16 that the purpose of the REMS is to make patients aware of
17 certain information concerning the risks that could affect
18 patients' decisions to use, continue to use -- to use or
19 continue to use Subsys. Do I see that right?

20 A. Yes. That was a big part of this REMS.

21 Q. Could you just explain that to the jury, what the
22 goal of the FDA was as explained in that sentence in the
23 approval letter?

24 A. Well, in that particular paragraph and sentence
25 because there are the risks that we've described and there

1 are other medications that can be used, in order for this
2 product to be used safely patients have to be adequately
3 counseled and informed on what the risks are and how to use
4 the product properly and situations in which they should
5 stop, or also warning signs of some of the more serious side
6 effects, when to get help, that sort of thing.

7 Q. Now, you said that there are multiple parts to what
8 the term TIRF REM requires. The first is that a doctor or a
9 prescriber sign up; is that right?

10 A. Yes.

11 MR. AFRAME: And if we could just pull up 103 for a
12 minute.

13 Q. Do you recognize that document?

14 A. Yes. That's the prescriber enrollment form.

15 Q. And it has a whole series of things that the
16 prescriber is agreeing to; is that right?

17 A. Yes.

18 Q. And what's the first one?

19 A. That the prescriber has reviewed the educational
20 program, the full labeling, the full prescribing information
21 for each of the TIRF medicines, and that they have taken the
22 test, the knowledge assessment, and that they understand the
23 responsible use conditions for the TIRF medicines and the
24 risks and benefits of chronic opioid therapy.

25 Q. And where do they get this education program?

1 Where is that available to the prescriber?

2 A. There's a website, the TIRF REMS website that has
3 all of the information, all of the forms, the educational
4 material.

5 Q. And where's the test?

6 A. It's in that material.

7 Q. And the second one is about understanding the drug
8 can be abused; is that right?

9 A. Yes. As a Schedule II opioid, that's a risk.

10 Q. And what does it tell that the prescriber is
11 supposed to do in regard to the risk of abuse?

12 A. The prescriber needs to know about the patient,
13 what the patient's history is, what risk factors they may
14 have for addiction or abuse, and take that into consideration
15 because of the risk with opioids for abuse and addiction and
16 also the risk factors for any given patient that might lead
17 to an accidental overdose, and also if patients are suicidal,
18 that's extremely important to know so that you're not giving
19 them medication that could lead to an intentional overdose or
20 suicide.

21 Q. And I should have asked you this question earlier.
22 For people who present with addiction, are there pain options
23 available other than a TIRF opioid?

24 A. Yeah, patients with a history of addiction,
25 especially if they have a history of opioid addiction, can be

1 very challenging to manage. It's very complicated when they
2 have pain.

3 First you try to avoid opioids as much as possible.
4 If the situation really can't be controlled with other
5 medicines, there's some drugs that are used both for pain
6 medicine and to treat addiction. So drugs like
7 buprenorphine, for instance.

8 Q. Is there another name that the jury might be
9 familiar with that's buprenorphine?

10 A. Yes. So Suboxone, Subutex, Butrans.

11 Q. Now, there's also -- there's a series after that
12 of -- a lot of things we already discussed, right, looking
13 down. It's for opioid tolerant patients. We've talked about
14 that already, right?

15 A. Yes.

16 Q. And who it's contraindicated for?

17 A. Yes.

18 Q. And it's not to be used for headaches and
19 migraines?

20 A. Yes.

21 Q. And No. 7 talks about the initial starting dose,
22 the doctor is agreeing that he or she understands that; is
23 that right?

24 A. Yes.

25 Q. I want to look at No. 8, though: I will provide a

1 medication guide for the TIRF medicine I intend to prescribe
2 to my patient and review it with them.

3 What is the medication guide?

4 A. Medication guides are part of products' labeling,
5 and it's patient labeling as opposed to prescriber labeling.
6 It's intended for patients so it's written in plain English
7 without some of the technical terms, and it's information
8 that we think is important for patients to have with the drug
9 that has the medication guide. So it typically has
10 information about what the drug is, what the drug is used
11 for, what the risks are, the warnings, and what to do if
12 certain things happen with side effects. For these products
13 it provides information about signs for when there may be --
14 they may be taking too high of a dose and on when to call the
15 doctor.

16 Q. Does every drug that's approved by the FDA have a
17 medication guide?

18 A. No. Medication guides are only used for products
19 where we think it's extremely important for patients to have
20 very specific information about the product.

21 Q. And for the TIRF drugs, does the FDA require a
22 medication guide?

23 A. Yes.

24 Q. So is there a medication guide for Subsys?

25 A. Yes.

1 Q. So if I turn to Government's Exhibit 101, do you
2 recognize this?

3 A. Yes. That's the medication guide for Subsys.

4 Q. And it says -- there's a box at the top. What is
5 that?

6 A. So this is the most important information for
7 patients and it's translating language from the label. So
8 the first important paragraph, the first paragraph is
9 basically letting patients know that they should already be
10 on a background around-the-clock opioid. And they -- I mean,
11 opioid tolerant is a little difficult to explain in a short
12 amount of writing so it advises patients to talk to their
13 health care provider to make sure they're opioid tolerant.
14 We worry terribly about exposure to children so it's telling
15 patients to keep it in a safe place and then when to get
16 emergency medical help. So any chance that a child has
17 gotten access to it, any adult who might have gotten access
18 to it and taken it, you know, anyone who wasn't prescribed
19 the medication because they can overdose and die from it, and
20 just to really underscore the same messaging, anybody who is
21 not opioid tolerant.

22 Q. And I think if we went through this first several
23 pages, do you agree with me that this covers in plain English
24 some of the material we've already talked about?

25 A. Yes.

1 Q. Now, if we went to the sixth page -- so there's
2 some diagrams. I guess what I want to know, does this
3 provide information more than just risk factors, this
4 medication guide?

5 A. Yes. For these products we have asked companies to
6 provide additional basically equipment to help patients store
7 it safely because we're that worried about accidental
8 exposures. So there's something called various names
9 depending on a product but a child safety kit. In this case
10 it's a pouch, that top one, that you can put -- you know, in
11 the setting of a person with cancer who has breakthrough pain
12 if they have to go to the doctor, if they are not in their
13 own home and they want to take some of the medication with
14 them, this is required to be made available for people so
15 that they have a safe way to carry the drug under more of a
16 locked protection than -- you know, our biggest fear is that
17 somebody is going to put it in a tissue in their pocket and
18 then it can fall out or what have you.

19 Q. So that's trying to give that guidance to the
20 patient?

21 A. Yes, and also to provide locks for cabinet doors so
22 that children can't accidentally -- again, basically to
23 childproof the cabinet where it's stored.

24 Q. Let me go forward a couple pages to another
25 diagram. And I think you demonstrated this. This is the

1 medication guide as well, right?

2 A. Well, this is instructions for use, which is part
3 of a long document that's labeled, but this is separate.
4 It's the instructions for use.

5 Q. And it's in the medication guide?

6 A. It's attached to the medication guide, but it's
7 technically a separate document.

8 Q. And so are these things that a prescriber must go
9 over with a patient before the drug is prescribed?

10 A. Yes. Even -- prescribers should go over all the
11 important safety information for any product, but the reason
12 why we've gone to such lengths with a restricted program like
13 the TIRF REMS, which really takes time and effort for
14 everyone involved, is because these products have the
15 potential to be more dangerous than others.

16 Q. And does the patient have to sign off as well?

17 A. Yes. There is a patient enrollment form that the
18 prescriber is supposed to review with the patient, discuss
19 with the patient, and the patient is supposed to sign
20 acknowledging that they've gotten all the information at the
21 time of the first prescription.

22 Q. And if we turn to 104. What is that?

23 A. That is the patient/prescriber agreement form
24 that's part of the TIRF REMS for these products.

25 Q. And number one says: My prescriber has given me

1 the medication guide for the TIRF medicine I've been
2 prescribed and has reviewed it with me?

3 A. Yes.

4 Q. And does it have several other acknowledgments that
5 relate to things we've already talked about, most of them?

6 A. Yes.

7 Q. Is this -- you're familiar with all the various
8 REMS going on at the FDA, are you?

9 A. Well, certainly all the drugs for pain management.

10 Q. Okay. So if you were to characterize this REM as
11 among all the other REMS that are going on in the area for
12 which you're the director, how would you characterize this
13 REM in its sort of strength of restriction? How onerous is
14 this one compared to others?

15 A. This is the most restrictive REMS for any pain
16 medicine and it's certainly the most restrictive in my
17 division, and it's about as restrictive as they get across
18 most drug products.

19 Q. Why does the FDA make that decision to use the most
20 restrictive REMS for Subsys?

21 A. Because the risk for harm was great. In a properly
22 and safely chosen patient with proper use, the benefit can
23 outweigh the risk, but because the risk was so significant
24 for these products, these extra layers were put in place to
25 enable prescribers and patients to use the products safely.

1 Q. And do those remain in place now?

2 A. Yes.

3 Q. Does the FDA have any desire on what the effect of
4 the REMS will be on sort of the demand for this drug?

5 A. We worry about that because it can be considered
6 burdensome, and the law says we need to minimize the burden
7 to the health care system. So that's why there's a shared
8 REMS, all the products just have one REM so a prescriber
9 doesn't have to enroll for each different product, but in
10 these cases it's also meant for the prescriber to stop and
11 think, A, this is in place so there's a reason for it, and
12 it's not -- you just can't simply write the prescription and
13 be done with it. You have to stop and go through all of this
14 material and understand the responsibilities of being a
15 prescriber for these drugs and your responsibility to the
16 patients as well.

17 Q. So what is it also supposed to make sure that the
18 patients have obtained before they -- ultimately does the
19 patient make the decision whether they want to go on the
20 drug?

21 A. The patient should always make the final decision,
22 and especially here, because there's responsibilities for the
23 patient both to understand the risks and also how to store it
24 safely and how to use it safely. Definitely not to share it.
25 That sort of thing.

1 Q. And does this make certain legal requirements to
2 make sure that patients have a certain amount of information
3 before making that ultimate decision?

4 A. I'm not quite sure --

5 Q. I guess what I'm asking is the medication guide you
6 told me is not for every drug. Not every drug had a
7 medication guide, right?

8 A. Correct.

9 Q. But I think you also told me it's required that the
10 patient get and have reviewed with them the medication guide
11 for this drug?

12 A. Yes. So typically prescribers are not required to
13 actually hand the medication guide or go over a medication
14 guide with a patient. They are most commonly distributed at
15 the pharmacy.

16 This REMS program changes that so that the --
17 because the medication guide has the information that we
18 think patients have to know, have to receive to be able to
19 make a decision about using the product and also how to use
20 it safely. So in this case the REMS includes the review of
21 the medication guide with the patient as one of its elements.

22 Q. And does that assure that the patient has complete
23 knowledge before making that ultimate decision?

24 A. Certainly a lot of knowledge, yes.

25 Q. Everything in the medication guide?

1 A. Yeah, the patient should also, you know, know about
2 alternatives. This is not the only pain medicine so they
3 should have an understanding of why this medicine is being
4 chosen for them and, you know, this information about the
5 product, and if they have concerns what other options should
6 be. That's just good standard practice.

7 MR. AFRAME: Thank you, Dr. Hertz.

8 THE COURT: Cross-examination.

9 MR. RICHARD: Thank you, your Honor.

10 CROSS-EXAMINATION

11 BY MR. RICHARD:

12 Q. Good morning. Doctor, you've been with the Food
13 and Drug Administration for how long now?

14 A. 20 years.

15 Q. 20 years. Before that did you have a private
16 practice?

17 A. I was in a hospital-based practice.

18 Q. Okay. And when did you stop in the hospital-based
19 practice?

20 A. In 1999.

21 Q. 1999. And did you have a pain-based treatment?

22 A. Yes. As a neurologist, we definitely do some pain
23 management.

24 Q. Okay. Was that the main focus of your practice?

25 A. No. It was epilepsy. About a third of my practice

1 was epilepsy. The rest was general neurology.

2 Q. Okay. About how many patients did you treat a year
3 for pain?

4 A. Oh, my gosh, I'm sorry. I didn't prepare that.

5 Q. That's okay. If you remember.

6 A. It was quite a bit because we would get a lot of
7 people who had back pain, pain resulting from strokes, from
8 multiple sclerosis, and a lot of migraine patients. So it's
9 been a really long time.

10 Q. All right. You treated them in a whole number of
11 ways I'm sure when you were treating them for pain?

12 A. Yes.

13 Q. It wasn't always with drugs?

14 A. Correct.

15 Q. You also treated them with physical therapy?

16 A. Yes, or complementary medicine, acupuncture.

17 Q. Okay. And sometimes those things wouldn't work for
18 certain people's pain, correct?

19 A. Correct.

20 Q. And there are also injections that are done; isn't
21 that correct?

22 A. There are different types of injections done for
23 treating certain kinds of pain.

24 Q. Okay. And what type of injections are those?

25 A. There's a number. I as a neurologist was not

1 trained in doing those injections. Mostly they're steroids,
2 but there can be other types of medicines injected and those
3 patients would be referred to pain clinics with
4 anesthesiologists who most often do those treatments.

5 Q. Okay. And those were people that, I don't know if
6 they were specialists, but they focused on treating pain?

7 A. Yes.

8 Q. And when those things wouldn't work, is that when
9 you would -- would prescribing medication be your last
10 approach to treating pain?

11 A. That's a very big question, believe it or not. It
12 all depends on what the pain is, what it's from, how severe
13 it is. Some pain can respond to non-drug treatment.

14 For chronic pain it's often best to try an approach
15 that uses many different things concurrently. So physical
16 therapy and some medication perhaps and some other targeted
17 therapies.

18 Q. So those non-medicinal therapies sometimes didn't
19 work for people that were in pain, correct?

20 A. Correct.

21 Q. So then that's when sometimes you had to resort to
22 prescribing solely medication?

23 A. Yes, or sometimes they would be tried concurrently.

24 Q. Okay. All right. Some of those medications that
25 you would prescribe would be opioids?

1 A. Yes.

2 Q. Okay. And did you ever prescribe fentanyl as a
3 pain medication?

4 A. So my practice is so old that a lot of these
5 medicines were not available. I believe I may have
6 prescribed the patch form before I left practice.

7 Q. All right. So fentanyl -- fentanyl has been around
8 for decades you said, right?

9 A. (Nods affirmatively.)

10 Q. And it was initially just for anesthesia?

11 A. Yes, it was a part of what's called balanced
12 anesthesia.

13 Q. And that was done intravenously?

14 A. Yes.

15 Q. So was it through like a drip or a needle? How was
16 it done?

17 A. So in the operating room it would be administered
18 as needed but based on the judgment of an anesthesiologist.

19 Q. So an anesthesiologist is a doctor?

20 A. Yes.

21 Q. So the doctor would make the decision how it would
22 be used?

23 A. Yes, the anesthesiologist is managing all the drugs
24 in the operating room.

25 Q. Okay. And somewhere over the decades it somehow

1 was seen that it could be used in other ways, correct,
2 fentanyl?

3 A. Yes.

4 Q. And that wasn't the original reason that fentanyl
5 was approved, correct?

6 A. Correct.

7 Q. And the approval came from the FDA?

8 A. Yes.

9 Q. Okay. So essentially fentanyl itself became
10 off-label?

11 A. I don't quite understand.

12 Q. The original approval for fentanyl was for
13 anesthesia, correct?

14 A. Yes.

15 Q. And it became for pain treatment, correct?

16 A. Yes.

17 Q. And is that essentially the only way it's used now
18 or is it still used for anesthesia?

19 A. It's still used as part of balanced anesthesia.
20 It's used immediately after surgery sometimes by IV with a
21 button so patients can try and control their pain, and then
22 it's used in the other forms.

23 Q. All right. So since it was initially approved as
24 an anesthesia medication, fentanyl, and then it became used
25 as a pain medication, that essentially is off-label; isn't

1 that correct?

2 A. No, it was approved for use as a pain medication.
3 So that was a new indication added on separately for the
4 other products.

5 Q. Okay. And how is that approved? Do you know?

6 A. Clinical studies are conducted and the information
7 is submitted to the FDA and it's reviewed and a decision is
8 made about whether the product should be approved.

9 Q. Would those studies have been done by the FDA or by
10 a private corporation?

11 A. Companies typically do the studies that support an
12 indication for their drug.

13 Q. Okay. And do you by any chance know which was the
14 first company to change it from being for anesthesia to pain
15 meds?

16 A. I don't know about the IV per se, but the first
17 patch type product was I believe Janssen Pharmaceuticals.

18 Q. Do you know what year that was that that got
19 approved?

20 A. I believe it was in the '90s.

21 Q. In the '90s?

22 A. I don't know the year.

23 Q. All right. So it was found out that fentanyl would
24 be used as a pain medicine that could be absorbed through the
25 skin, correct?

1 A. Yes.

2 Q. Now, fentanyl itself, it's really just one chemical
3 compound, correct?

4 A. Yes.

5 Q. It doesn't change ever?

6 A. It gets metabolized by the body.

7 Q. Okay. Does it become -- I think the best way to
8 ask it is -- so there's a chemical compound that's known as
9 fentanyl, correct? If that chemical compound changes, it is
10 no longer fentanyl, correct?

11 A. It depends how it's changed.

12 Q. Okay.

13 A. So small modifications to fentanyl resulted in
14 these other drugs I mentioned earlier, some of which are even
15 more potent than fentanyl.

16 Q. Okay. All right. Now, but the fentanyl that you
17 get in a patch is the same fentanyl that would have been
18 given intravenously in the older days?

19 A. Yes.

20 Q. Okay. So it doesn't change its chemical compound
21 from once it's fentanyl it stays fentanyl when it becomes a
22 patch?

23 A. Products -- different products can be made with
24 fentanyl in it. If it's called fentanyl, it's the same
25 chemical.

1 Q. Okay. And the delivery system of Subsys, that
2 essentially is -- is it a liquid?

3 A. Yes.

4 Q. Okay. And it's in that little device where you
5 spray it under your tongue?

6 A. Yes.

7 Q. Okay. But it's fentanyl?

8 A. Yes.

9 Q. And it's the same fentanyl that's been around for
10 decades?

11 A. Yes.

12 Q. It's simply in a different delivery system?

13 A. Yes.

14 Q. And that delivery system is that little device?

15 A. For Subsys, yes.

16 Q. Okay. All right. And initial approval of Subsys
17 was done you said over a year period of time?

18 A. The review period, yes.

19 Q. So what would happen is Insys -- the company that
20 made Subsys is Insys, correct?

21 A. Yes.

22 Q. Over a certain period of time they did studies?

23 A. Yes.

24 Q. And they collected data, correct?

25 A. Yes.

1 Q. And then they present that to the FDA?

2 A. Yes.

3 Q. Okay. And the FDA over in this case a year gave
4 approval?

5 A. Yes.

6 Q. Okay. But with conditions obviously, correct?

7 A. Approval means that it's approved based on the
8 indication and label that's agreed upon at the time of
9 approval. So approval doesn't mean -- it means a very
10 specific thing.

11 Q. When you say agreed upon, who is it agreed upon
12 with? Is it just people from the Food and Drug
13 Administration or between the Food and Drug Administration
14 and the corporation that made the application?

15 A. It's the two. It's the FDA and the company that's
16 sponsoring the product.

17 Q. Okay.

18 A. So if they don't like what we think is appropriate,
19 it may not get approved.

20 Q. Okay. Can they reapply then if it's not?

21 A. Oh, yes.

22 Q. Okay. So in this case with Subsys it was approved
23 for breakthrough cancer pain, correct?

24 A. In patients who are opioid tolerant on
25 around-the-clock opioids.

1 Q. Right. Okay. Now, that is --

2 A. And who have cancer.

3 Q. All right. So if I can go back through and review
4 my notes here.

5 So initially there were literally three conditions,
6 correct? That it be for -- breakthrough pain is one of them,
7 correct?

8 A. Uh-huh.

9 Q. Okay. One is for prior opioid therapy?

10 A. Uh-huh.

11 Q. And then opioid tolerant people?

12 A. Yes, and cancer pain.

13 Q. And cancer pain, okay. When I say breakthrough
14 pain, it's for breakthrough cancer pain?

15 A. Breakthrough pain in patients with cancer, yes.

16 Q. What's the difference between cancer pain and any
17 other type of breakthrough pain?

18 A. It's very controversial if any other kinds of pain
19 actually can be defined as breakthrough instead of just
20 periods of pain.

21 In patients with cancer, physicians who were caring
22 for them noted this kind of spikey type of pain on top of the
23 background pain and that was where the concept of
24 breakthrough pain was really defined, and that's why these
25 drugs were studied in that population. That's not

1 necessarily the case with other pain syndromes.

2 Q. When you say spikey -- I suppose I can say it in
3 words maybe everybody can understand. So it's almost like a
4 seismograph how there's a steady line, there's no movement,
5 and a spike is an uptick of pain?

6 A. Yes, that there would be a rapid onset of more
7 pain, and typically it would not last very long.

8 Q. Okay. Typically how long could it last?

9 A. Minutes, a half hour, an hour maybe.

10 Q. Depends on the patient?

11 A. Sure.

12 Q. Okay. And obviously with people's pain it depends
13 on the strength of the pain or the severity of the pain
14 depends on the patient as well?

15 A. Yes.

16 Q. Okay. All right. And so this breakthrough pain, I
17 mean -- so Subsys is only for breakthrough cancer pain,
18 correct?

19 A. That's what it was approved for.

20 Q. Okay. What's the difference between the
21 breakthrough cancer pain and any breakthrough pain?

22 A. Well, some doctors may argue that breakthrough pain
23 only happens in cancer. Others may argue that it happens in
24 other conditions.

25 Q. Okay. And there are other conditions where people

1 have spikes in pain or at least they communicate that to the
2 doctors, correct?

3 A. Yes.

4 Q. Okay. And what is -- I guess to explain it,
5 there's differing opinions on which pain is real?

6 A. No, patients are believed if they have pain.

7 Q. Okay.

8 A. The question is whether or not the type of
9 breakthrough pain that occurs in other conditions is similar
10 to the breakthrough pain that occurs in cancer patients and
11 if it should be treated the same way. That's where the
12 differences may exist.

13 Q. Okay. So -- I'll walk away from that for now.

14 There's also the discussion of opioid therapy.
15 This substance was approved for people that were already on
16 opioid therapy?

17 A. Yes.

18 Q. So opioid therapy are different drugs that patients
19 are taking on a regular basis, correct?

20 A. Yes. In this case it was for around-the-clock
21 therapy, meaning they were on a schedule of an opioid, not
22 just taking it as needed.

23 Q. So when you say a schedule, does that mean you
24 would get let's say a pill bottle or a patch and it would
25 tell you how often you had to use it and when to use it?

1 A. Yes. If the pain was not adequately managed with
2 occasional taking medication as needed, the patient and the
3 prescriber would work out a medication to use
4 around-the-clock that would be every eight hours or every
5 twelve hours depending on what the medicine was.

6 Q. Okay. And the third condition was that there had
7 to be an opioid tolerance?

8 A. Yes.

9 Q. That means the patient had to have been on opioids
10 prior to being on the Subsys, correct?

11 A. On at least a minimum amount for a minimum length
12 of time. Because if somebody really just needed a small
13 amount of around-the-clock opioid, they may not be
14 sufficiently opioid tolerant to have adapted to some of the
15 side effects like respiratory depression.

16 Q. Okay. And the first one to decide opioid tolerance
17 would be the doctor, correct?

18 A. Well, we defined it in the product labeling and in
19 the TIRF REMS to help the doctor understand what the safe
20 conditions were that people were studied in and what opioid
21 tolerance was meant to be in this setting.

22 Q. Okay. And essentially the doctor was to decide
23 based on your guidelines from the FDA whether his specific
24 patient was opioid tolerant, correct?

25 A. Yes.

1 Q. Okay. And that's because that doctor had more of a
2 history with the patient?

3 A. Hopefully, yes.

4 Q. All right. Now, you discussed earlier -- we talked
5 a little bit about being off-label. A lot of medications are
6 off-label, correct?

7 A. Yes.

8 Q. Okay. So the FDA approves, like in this case for
9 breakthrough cancer pain, this drug Subsys?

10 A. Yes.

11 Q. Many drugs are used off-label?

12 A. Yes.

13 Q. And it's usually the doctors who decide -- well, it
14 is the doctors who decide whether it's used off-label,
15 correct?

16 A. Yes.

17 Q. Okay. And again, that is because the doctors know
18 the patients better than the FDA, these specific patients?

19 A. The FDA doesn't know patients.

20 Q. Right.

21 A. If the physician thinks the product may be suitable
22 for that situation.

23 Q. Okay. So in this case the FDA said this medication
24 was approved for breakthrough cancer pain?

25 A. Yes.

1 Q. Okay. There was no ban to say it couldn't be used
2 for other pain?

3 A. Correct.

4 Q. As long as it was done on the TIRF REMS schedule or
5 with their program?

6 A. Yes.

7 Q. Okay. All right. Now, some of those medications
8 that are TIRF -- TIRF again was a sublingual or not a --

9 A. Transmucosal.

10 Q. Thank you. One of those you mentioned was Actiq?

11 A. Yes.

12 Q. And you said it was like a lozenge on a stick?

13 A. Yes.

14 Q. Did it essentially look like a lollipop?

15 A. Unfortunately, yes.

16 Q. Okay. And you say unfortunately.

17 A. It raised our concern about childhood -- pediatric
18 exposures.

19 Q. Okay. Were there other studies on how much
20 medication patients were actually getting from the Actiq when
21 they were using it in the, I'm going to use it for lack of a
22 better term, the lollipop form?

23 A. Yes.

24 Q. And was that because a lot of patients were chewing
25 the medication?

1 A. No. I'm not sure I understand that question.

2 Q. It's in the form of a lollipop, correct?

3 A. A lozenge on a stick.

4 Q. A lozenge on a stick. And it was made to be rubbed
5 on the inside of the cheek?

6 A. Yes.

7 Q. Okay. There were patients that would bite it as if
8 it actually were a piece of candy, correct?

9 A. Possibly.

10 Q. Okay. When was Actiq approved?

11 A. I believe about '95.

12 Q. Okay. And at that point you were still in
13 practice, correct?

14 A. Yes.

15 Q. Okay. Had you ever prescribed it?

16 A. No.

17 Q. Okay. All right. So your experience with Actiq
18 was simply with the Food and Drug Administration?

19 A. Yes.

20 Q. All right. You said there were other lozenge type
21 medications, correct, that were TIRF?

22 A. Not a lozenge per se but other types of TIRF
23 products, yes.

24 Q. Okay. And you had indicated some of them were to
25 be placed in the cheek and some of them were to be placed

1 underneath the tongue?

2 A. Yes.

3 Q. Okay. And are there studies to show how much
4 medication that was actually in the pill was actually getting
5 into the patients?

6 A. Yes.

7 Q. Okay. They weren't getting as much as if the
8 fentanyl that was in it was actually directly put into the
9 bloodstream?

10 A. None of them give the same amount as an injection.

11 Q. Okay. And were there concerns that some -- again,
12 TIRF was made to be made orally, correct, but not swallowed?

13 A. Well, transmucosal.

14 Q. Transmucosal, which means just inside the mouth?

15 A. Yeah.

16 Q. Okay. And if that medication made it into the
17 stomach, were there problems with that?

18 A. It was just less effective. Less would get to the
19 bloodstream to work on the pain.

20 Q. Okay. So if, for instance, a patient chewed on
21 like an Actiq lozenge on a stick and swallowed it, it
22 wouldn't be as effective as if it stayed in the mouth?

23 A. Correct.

24 Q. Okay. All right. And that would be the same for
25 any type of lozenge medication?

1 A. The same for Subsys, if they swallowed the liquid.

2 Q. Okay. So the Subsys was made to be absorbed
3 directly under the tongue, correct?

4 A. Uh-huh.

5 Q. And again, you had indicated there's no -- the FDA
6 doesn't take a stance on which is superior, whether it be
7 Subsys or Actiq or any other drug?

8 A. In order to determine if one drug is superior to
9 the other, we require that the companies actually study it
10 that way, do a comparison in a clinical study, and then we
11 have data that actually shows a direct comparison.

12 Q. Okay. So there has to be detailed data as to
13 whether one drug is superior to another?

14 A. Yes.

15 Q. Okay. That would allow a drug company to advertise
16 saying they're superior?

17 A. Yes, as long as there's replicated evidence. So at
18 least two studies showing that superiority. That's the
19 requirement for us to agree that there's a superiority claim.

20 Q. Okay. Essentially then it's up to a doctor to
21 decide which medication is better to prescribe, correct?

22 A. Yes.

23 Q. Okay. The FDA again takes no stance on which
24 medication is better to treat which patient?

25 A. Correct. Among these different TIRF medicines I

1 assume you mean?

2 Q. Yes.

3 A. Okay, yes.

4 Q. Okay. Now, you had mentioned earlier that there
5 were issues with prescribing Subsys to those with respiratory
6 issues?

7 A. Yes.

8 Q. There's not an outright ban on that, correct?

9 A. No, not on that one.

10 Q. I should say back in 2013 and '14 was there a ban
11 on TIRF products being used for respiratory issues?

12 A. I'm not quite -- I'm not sure how to answer that.

13 Q. Okay. Let me ask you a couple things first then.

14 Around 2013 or '14 things started to change about
15 how people thought about -- or how the FDA felt about opioids
16 being prescribed, correct?

17 A. No.

18 Q. Did studies come out saying that the effect of
19 opioids on addictive -- on addiction was actually
20 underestimated?

21 A. No. The data had been pretty consistent, and if
22 you look back at the labels from the original approval of
23 Actiq, they were very clear on the risk even back in '95.
24 That's not new. The REMS is new because of our authority,
25 but Actiq was approved with a risk map which was what was

1 available to us as a tool at that time.

2 Q. Okay. Has the REMS program changed since around
3 2012?

4 A. It's changed a few times.

5 Q. Okay. Has it become more restrictive?

6 A. No.

7 Q. Has it become more supervised by the Food and Drug
8 Administration?

9 A. No.

10 Q. Okay.

11 A. I'm not sure exactly what you're getting at there
12 but --

13 Q. That's okay. So as to Subsys regarding respiratory
14 prescription, back in 2013 or '14 there was no ban on using
15 Subsys for people with respiratory issues?

16 A. Do you mean a contraindication?

17 Q. Correct.

18 A. Yes, there was no contraindication for use in
19 people with respiratory conditions.

20 Q. Okay. But there was an advisory for doctors to
21 keep an eye out on their patients if they prescribed it and
22 they had respiratory issues, correct?

23 A. There were warnings in several parts of the
24 labeling, including the boxed warning, about the risk, yes.

25 Q. Okay.

1 MR. RICHARD: Could I just have a moment, your
2 Honor?

3 THE COURT: You may.

4 (Attorney Richard confers with Attorney Gagne and
5 the defendant)

6 MR. RICHARD: Nothing further, your Honor.
7 Thank you.

8 THE COURT: Redirect.

9 MR. AFRAME: Just a few more questions, Dr. Hertz.

10 REDIRECT EXAMINATION

11 BY MR. AFRAME:

12 Q. When you said that the drug company submits the
13 studies that the FDA then reviews to ultimately approve the
14 drug, so the studies submitted by Insys, what was the
15 population that they studied their drug in?

16 A. Cancer patients with breakthrough pain who were on
17 around-the-clock opioids and who were tolerant to opioids.

18 Q. So you talked about this, there can be discussion
19 back and forth between the company and the FDA about what
20 something is approved for?

21 A. Yes.

22 Q. Was there any issue about whether this was for
23 cancer breakthrough pain?

24 A. No.

25 Q. We've talked a lot about the TIRF REMS Access

1 program. Does the requirement to follow that program depend
2 in any way on whether the decision by the doctor is so-called
3 on-label or off-label?

4 A. No.

5 Q. Let me ask that in a better way. Is the TIRF REMS
6 Access program required even when a doctor prescribes the
7 drug off-label?

8 A. Yes. The REMS is intended to mitigate risk, and
9 the risk is part of the drug no matter who gets it. So the
10 REMS does not require it be used in cancer patients. The
11 REMS requires it be used in opioid tolerant patients on
12 around-the-clock therapy and follow all of the other warnings
13 and contraindications.

14 Q. You -- it sounds like you were in practice when
15 some of these TIRF drugs were on the market?

16 A. Just Actiq.

17 Q. And you said you never prescribed it?

18 A. Correct.

19 Q. Why not?

20 A. I never had a patient with a significant enough
21 need. Patients who have that level of pain, there's not a
22 lot of them, so I never had anyone who quite met those
23 criteria.

24 Q. In your practice and your understanding are there
25 non-intravenous pain medications any more potent than the

1 ones we're talking about now?

2 A. Non-intravenous?

3 Q. Yes.

4 A. We just approved one for use only in the hospital
5 that it goes under the tongue. It's sufentanil, which is
6 more potent than fentanyl, but it's not available for use in
7 outpatients. Only in the hospital.

8 Q. So for outpatient use are the TIRFs the most potent
9 that are available?

10 A. Yes.

11 Q. The last question I have, there was some
12 questioning to you about Insys and how it could compare
13 itself to other drugs and you said what the requirements
14 were.

15 Did Insys submit to the FDA the necessary studies
16 for it to advocate itself as better than the other TIRF
17 drugs?

18 A. No.

19 MR. AFRAME: No further questions, Judge.

20 THE COURT: Cross?

21 MR. RICHARD: Nothing, your Honor. Thank you.

22 THE COURT: You may step down. You're excused.

23 Thank you.

24 MR. ROMBEAU: The government calls Dori Lefebvre,
25 your Honor.

1 DORI LEFEBVRE

2 having been duly sworn, testified as follows:

3 THE CLERK: For the record, please state your full
4 name and spell your last name.

5 THE WITNESS: Dori Lefebvre, L-E-F-E-B-V-R-E.

6 THE CLERK: Thank you. Please be seated.

7 MR. ROMBEAU: May I proceed, your Honor?

8 THE COURT: Yes.

9 DIRECT EXAMINATION

10 BY MR. ROMBEAU:

11 Q. Good afternoon, Ms. Lefebvre. Could you tell the
12 jury where you currently work?

13 A. I work for the New Hampshire Board of Medicine.

14 Q. And what do you do there?

15 A. I am an investigator.

16 Q. What exactly is the New Hampshire Board of
17 Medicine?

18 A. They're responsible for licensing physicians and
19 physician assistants and investigating complaints against
20 those licensees.

21 Q. Are nurses subject to the Board of Medicine, or is
22 it a separate entity?

23 A. No, nurses fall under the Board of Nursing.

24 Q. And what do you do at the New Hampshire Board of
25 Medicine?

1 A. What do I do? I investigate doctors and physician
2 assistants.

3 Q. Do you have a particular title?

4 A. Fraud investigator. I also have the title medical
5 board investigator.

6 Q. And so what does that mean your day looks like?
7 What are you doing on a daily basis in that role?

8 A. Well, I review information coming into the medical
9 board on a daily basis. Mainly consumer complaints, lawsuits
10 against licensees of the board, other information that comes
11 in in various ways, and determine whether or not it's
12 appropriate to open an investigation or not.

13 Q. And how long have you worked at the Board of
14 Medicine?

15 A. 18 years.

16 Q. As part of your job there are you generally
17 familiar with the rules and regulations that apply to
18 physician assistants here in New Hampshire?

19 A. Yes.

20 Q. Okay. What exactly is a physician assistant?

21 A. A physician assistant is a person that has had two
22 years of training in a physician's assistant program. They
23 also have to pass a national examination and have to have a
24 couple of reference letters from physicians that can attest
25 to their skills, and they also are required to have a

1 responsible supervising physician as well as an alternate
2 supervising physician on record with the board.

3 Q. So can a physician assistant practice on his or her
4 own, like an independent, and hang up a shingle?

5 A. No, they have to practice under a responsible
6 supervising physician or alternate if a responsible
7 supervising physician, also known as an RSP, is not
8 available.

9 Q. Okay. And what is a physician's assistant
10 authorized to do in terms of practicing medicine?

11 A. They can practice under the scope of their
12 supervising physician. So if they're a family practitioner,
13 it would be expected that they could act as a primary care
14 doctor for a patient. They're allowed to prescribe and order
15 and do, you know, a lot of the same things that a physician
16 can do.

17 Q. And for the supervisory physician, is that a
18 specific identified doctor for each physician assistant that
19 has to be --

20 A. Yes.

21 Q. Okay. Can you tell the jury a little bit about
22 that process? How does the Board of Medicine keep track of
23 that?

24 A. Well, it has to be in writing. The RSP has to
25 agree to become the PA's assistant. They do sign a form that

1 indicates that it's kept on record at the medical board and
2 it's tracked at the medical board who the supervising
3 physicians and alternates are for each PA.

4 Q. And so if there's a change, does that require
5 something to be submitted to the board?

6 A. Yes.

7 Q. And generally speaking, what is the role of the
8 supervisory physician in overseeing the PA?

9 A. They're supposed to be available to the PA to
10 answer questions. They don't have to be on-site, but they do
11 have to be available so, you know, they may need to call
12 them. That's okay. If they're in a different location,
13 that's absolutely fine. The RSP should be meeting on a
14 regular basis with the physician assistant every week or so
15 going over cases, be available to answer questions, that sort
16 of thing.

17 Q. Does the Board of Medicine have an expectation that
18 the supervisory physician is signing off on everything that
19 the PA does?

20 A. No. They don't sign off on everything that a PA
21 does, no.

22 Q. And I think you mentioned at the outset the Board
23 of Medicine has some role in the licensing of PA's; is that
24 correct?

25 A. Yes.

1 Q. How often does a PA have to renew a license with
2 the Board of Medicine?

3 A. Annually.

4 Q. And are they required to keep any sort of national
5 licensure current as part of that process?

6 A. Yes. That's my understanding, yes.

7 Q. Can a physician assistant prescribe controlled
8 substances here in New Hampshire?

9 A. They can if they have DEA registration in place, if
10 they have a DEA number to do that.

11 Q. And so that's not something the Board of Medicine
12 decides?

13 A. It's not a requirement for licensure that you have
14 a DEA number that allows you to write for controls.

15 Q. So the determination of whether a particular
16 physician assistant can or cannot prescribe controlled
17 substances, does that come from whether or not they have a
18 DEA license?

19 A. Yes.

20 Q. Okay. Do you know the defendant, Chris Clough, in
21 this matter?

22 A. Yes.

23 Q. Have you met him before?

24 A. Yes.

25 Q. Do you see him in the courtroom here today?

1 A. Yes.

2 Q. Can you just for the record identify him?

3 A. He's the gentleman over to my right with glasses,
4 light-colored hair, a black jacket.

5 MR. ROMBEAU: Your Honor, I would just ask the
6 record to reflect that the witness has identified the
7 defendant.

8 THE COURT: It does.

9 Q. Was Mr. Clough a licensed physician assistant in
10 the state of New Hampshire in the time period of 2013 and
11 2014?

12 A. Yes.

13 Q. At some point in that time frame, in 2014, was
14 there a complaint filed with the Board of Medicine regarding
15 Mr. Clough?

16 A. I believe so.

17 Q. And in August of 2014 did the board schedule that
18 matter for a hearing?

19 A. Yes.

20 Q. Generally speaking when the board schedules
21 something like that, is it a long time out or something very
22 short-term about to happen?

23 A. I've seen it both ways. I've seen hearings occur
24 very quickly and others that are, you know, way down the
25 road.

1 Q. And do all matters go to a hearing?

2 A. No.

3 Q. Generally speaking, is it pleasant news for a
4 provider to get notice that they have a matter going to a
5 hearing?

6 A. No.

7 Q. And did the complaint against Mr. Clough in fact
8 proceed to a hearing at some point in 2014?

9 A. Yes.

10 Q. Are you familiar with that hearing?

11 A. Yes.

12 Q. Okay. Is it a one-day type thing or does it go
13 longer?

14 A. I think it was multiple days.

15 Q. And was that in this instance spread out over many
16 months?

17 A. I believe so.

18 Q. Did you review some transcripts from that hearing
19 in preparation for your testimony here today?

20 A. Yes.

21 Q. Did Mr. Clough testify at that hearing in April of
22 2015?

23 A. Yes.

24 Q. Was he placed under oath as a part of that
25 testimony?

1 A. Yes.

2 Q. Did he answer questions from the attorneys and
3 board members present at the hearing?

4 A. Yes.

5 MR. ROMBEAU: Could we pull up Exhibit 110, please.

6 Q. You should have on the screen in front of you, Ms.
7 Lefebvre, Exhibit 110. Do you recognize this?

8 A. Yes.

9 Q. What are we looking at here?

10 A. This is the transcript of the hearing.

11 Q. And what was the date of this particular day?

12 A. This looks like day five of the hearing, April
13 14th, 2015.

14 Q. And could we go to page two, please.

15 We've provided only the portions I'm going to ask
16 you about here, Ms. Lefebvre. Is this the portion where Mr.
17 Clough was sworn and put under oath?

18 A. Yes.

19 MR. ROMBEAU: Could we go to the next page, please,
20 Dena.

21 Q. During the course of his testimony was there a
22 question and answer type format, Ms. Lefebvre?

23 A. Yes.

24 Q. For ease of understanding this, would it be all
25 right if I read the question and asked you to read his

1 answers under oath?

2 A. Yes.

3 Q. Okay. So at the bottom of the page here the
4 question reads:

5 Your prior supervisory physician, and correct me if
6 I'm wrong, from February of 2011 until September of 2014 was
7 Dr. John Schermerhorn.

8 What was Mr. Clough's answer?

9 A. Yes.

10 Q. Next question:

11 And your current supervisory physician is Dr. David
12 Tung?

13 A. Correct.

14 Q. The next portion at the bottom of the page. I'll
15 just start with the question here:

16 Moving on to prescribing, how would you describe
17 your opiate prescribing philosophy if you have one?

18 And what was Mr. Clough's response to that
19 question, and I know this is a long one.

20 A. The philosophy, it's an evolving philosophy in
21 terms of -- it's one of the things that Dr. Fanciullo didn't
22 mention, you know, in the early '90s the mantra was, you
23 know, treat pain and treat it aggressively. There were all
24 these studies by Russ Portnoy and his colleagues and I'm not
25 good at recalling the names of those studies, and so that was

1 kind of the general philosophy to treat pain. What I do is I
2 see people, I talk to them, I examine them and I come up with
3 a plan. Pain is one of those things where you just can't
4 look at someone and say, well, you know, you're hurting right
5 now, so you have to in part rely on the patient's history and
6 you have to trust your patients to a degree, although that's
7 not the way, you know, it sort of is in pain management. We
8 have to have some, I don't know if skepticism is the right
9 word, but I'm aware of the issues in the community. So my
10 philosophy has kind of developed from all those early studies
11 which said, you know, treat pain and treat it aggressively,
12 and those studies have since been, I don't know if undermined
13 is the word, but Russ Portnoy has come out and said he
14 overstated the benefits of treating chronic pain and I think
15 that was in 2011, 2012, or maybe 2013. And so the new trend
16 is to back off on the opiates and that's essentially what
17 we've been doing or what I've been doing.

18 Q. Before I move on to the next one, I just want to
19 ask, are you familiar with the name Dr. Fanciullo?

20 A. Yes.

21 Q. Was he a witness at this particular proceeding?

22 A. Yes.

23 MR. ROMBEAU: If we could go to the next page,
24 Dena.

25 Q. I'll read this next question to you from the

1 record:

2 And would you agree that before prescribing opioids
3 to a patient you must discuss the risks and benefits of
4 opiate therapy with the patient?

5 What was Mr. Clough's answer?

6 A. Yes.

7 Q. If you go to the next page, the next question that
8 we'll cover is:

9 Let's move on to sort of the hypothetical approach
10 for existing patients who are already in the practice who are
11 already on opioids for pain management. Once you start
12 prescribing opioids to a patient for pain management, would
13 you agree that you should be monitoring the patient for signs
14 of overuse, misuse or abuse of the opioids?

15 What was his answer?

16 A. Correct.

17 Q. If you go to the next page, there are a few
18 questions we're going to cover here. Question reads:

19 And you would agree that for patients who are on
20 opioids part of what you need to do is to determine whether
21 or not the opioid therapy is actually working, correct?

22 A. Yes.

23 Q. Next question:

24 That would include potentially making modifications
25 to the opiate therapy if need be to seek proper objectives?

1 A. Yes.

2 Q. Next question was:

3 And if those objectives are not being achieved, you
4 need to assess whether or not it's appropriate to keep the
5 patient on the opiates whether it be the quantity or the
6 dosage?

7 A. Yes.

8 Q. Final question is:

9 You would also need to know if the patient is
10 exhibiting signs of misuse or abuse or overuse of their
11 prescription, right, and you would also need to reassess if
12 there's evidence of that?

13 A. Correct.

14 Q. Okay. And then the last page I'll just refer you
15 to, is this the certification of the court reporter that this
16 was an accurate transcription from that event?

17 A. Yes, it is.

18 MR. ROMBEAU: No further questions.

19 THE COURT: Cross-examination.

20 MR. RICHARD: Briefly.

21 CROSS-EXAMINATION

22 BY MR. RICHARD:

23 Q. Earlier in your testimony when you first began your
24 testimony you said there was a hearing in 2014, correct?

25 A. Yes.

1 Q. It was actually April 14th of 2015, correct?

2 A. This particular one is day five, so I don't know if
3 the hearing began in 2014.

4 Q. Okay. So if it started in '14, it could have been
5 continued for quite some time?

6 A. Yes.

7 Q. And here it's April so it's four months into 2015?

8 A. Yes.

9 Q. So that's normal for that to happen?

10 A. That could occur. The board meets one day a month.
11 So it's unusual if they'll meet or have a hearing more than
12 one day in one particular month, although I have seen it, but
13 it doesn't happen very often.

14 Q. Okay. But this testimony clearly from the
15 transcript is from April 14, 2015?

16 A. Yes.

17 MR. RICHARD: Nothing further, your Honor.

18 THE COURT: Any redirect?

19 MR. ROMBEAU: Just very briefly, your Honor.

20 REDIRECT EXAMINATION

21 BY MR. ROMBEAU:

22 Q. The scheduling of the matter for a hearing, Ms.
23 Lefebvre, did that occur in August of 2014?

24 A. The -- repeat the question.

25 Q. When this particular matter was scheduled for a

1 hearing and notice was given to the parties, did that occur
2 in August of 2014?

3 A. That sounds correct.

4 MR. ROMBEAU: Nothing further.

5 MR. RICHARD: Nothing based on that.

6 THE COURT: You're excused. Thank you.

7 All right. We're going to take the lunch break.
8 What I would like you to do is -- usually we take an hour.
9 We'll do that now and we'll see how it goes. If we want to
10 adjust it one way or the other we can, but generally just
11 stay in the general neighborhood area, get yourself something
12 to eat, you can stay right here if you would like, do
13 whatever you like to do, but we're going to reconvene at 1:30
14 p.m.

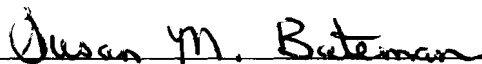
15 Remember my instructions, of course. No
16 discussions with each other or anyone else regarding the
17 trial during the recess.

18 (RECESS)
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C E R T I F I C A T E

I, Susan M. Bateman, do hereby certify that the foregoing transcript is a true and accurate transcription of the within proceedings, to the best of my knowledge, skill, ability and belief.

Submitted: 1-7-2019


SUSAN M. BATEMAN, LCR, RPR, CRR
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